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No.

IN THE
Supreme Court of the United States

CARDIAC PACEMAKERS, INC. and
GUIDANT SALES CORPORATION,
Petitioners,

and

MIROWSKI FAMILY VENTURES, LLC
and ANNA MIROWSKI,
Petitioners,

v.

ST. JUDE MEDICAL, INC.
and PACESETTER, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

J. MICHAEL JAKES
KARA F. STOLL
MICHAEL V. O'SHAUGHNESSY
FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
(202) 408-4000

Counsel for Petitioners Cardiac Pacemakers, Inc. and Guidant Sales Corporation

ARTHUR I. NEUSTADT
Counsel of Record
BARRY J. HERMAN
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, L.L.P.
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000

SIDNEY J. SILVER
SILVER, FREEDMAN & TAFF, L.L.P.
3299 K Street, NW
Suite 100
Washington, DC 20007
(202) 295-4500

Counsel for Petitioners Mirowski Family Ventures, LLC and Anna Mirowski

QUESTIONS PRESENTED FOR REVIEW

A widespread difficulty in patent litigation is the long period necessary to resolve a case. This case is about to enter its 14th year. In many instances, the delay is attributable to permitting the defendant upon remand to raise previously available but not previously asserted defenses. A first question is

1. Should a defendant be permitted to use "the accident of a remand" to raise previously available but not previously asserted defenses?

Patent protection is important for an economy heavily based upon technology. Although this Court recently held in one context that method and product inventions should be treated similarly (*Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109 (2008)), the Federal Circuit's *en banc* decision in another context does not provide such similar treatment and significantly restricts protection for method inventions. Two additional questions are

2. Where the value of a method invention is its availability for use if needed, should damages for infringement be restricted to actual use?

3. Should the maker of a product capable of performing a patented method be liable for products made here but sold abroad, *i.e.*, does 35 U.S.C. §271(f) exclude method claims?

CORPORATE DISCLOSURE STATEMENT

1. Mirowski Family Ventures, LLC states that it has no parent corporation and no publicly held company owns 10% or more of its stock.

2. Boston Scientific Corporation is the parent corporation of Guidant Corporation, which is the parent corporation of Cardiac Pacemakers, Inc., which is the parent corporation of Guidant Sales Corporation.

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OPINIONS BELOW

The Federal Circuit's 2009 *en banc* decision is reported at 576 F.3d 1348, its 2008 panel decision is reported at 303 Fed. Appx. 884, its decision vacating the 2008 panel decision to rehear the §271(f) issue *en banc* is reported at 315 Fed. Appx. 273 and its 2004 decision is reported at 381 F.3d 1371. The district court's 2007 invalidity decision is reported at 483 F.Supp.2d 734 and its 2006 damages decision is reported at 418 F.Supp.2d 1021.

JURISDICTION

The Federal Circuit's *en banc* decision was entered on August 19, 2009. The basis for this Court's jurisdiction is 28 U.S.C. §1254(1).

STATUTES

The involved statute (third question) is 35 U.S.C. §271(f).

STATEMENT OF CASE

Factual Background

Petitioners are Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC and Anna Mirowski (collectively "Cardiac"). Respondents are St. Jude Medical, Inc. and Pacesetter, Inc. (collectively "St. Jude").

The patent in suit, United States patent 4,407,288 ("the '288 patent"), is directed to an externally programmable implantable heart stimulator.

Implantable pacemakers have been in existence since 1958, but implantable defibrillators were not developed until much later. Indeed, amid much skepticism, the inventors of the '288 patent - Drs. Mieczyslaw Mirowski and Morton Mower, cardiologists from Sinai Hospital, Marlin Stephen Heilman, founder of the medical imaging company Medrad, and Alois Langer, an electrical engineer at Medrad - were pioneers in the field and successfully implanted the first implantable defibrillator in February 1980. For this achievement, they were inducted into the National Inventors Hall of Fame.

This first implantable defibrillator was a very basic device, including a pulse generator, leads from the pulse generator to the heart, and a power source. While a pioneering invention, it detected only fibrillation and, in response, delivered a high-energy defibrillation shock to the heart. It could not be

programmed or provide treatment modes other than defibrillation.

The '288 patent discloses a highly versatile, externally programmable and implantable heart stimulator. Unlike the pioneering but rudimentary defibrillator implanted in 1980, the stimulator disclosed in the '288 patent can detect various arrhythmias, including bradycardia, tachycardia, and fibrillation, and automatically provide the desired treatment for each arrhythmia, including pacing, cardioversion, and defibrillation. The invention includes one or more microprocessors, which can be programmed externally, after the stimulator has been implanted in a patient, to vary the treatment mode applied in response to a detected arrhythmia.

Moreover, in addition to conventional single modes of treatment (e.g., pacing, cardioversion, and defibrillation), the invention can be programmed to provide "multi-mode" therapy, meaning that the stimulator can respond to a single arrhythmia with one type of electrical therapy and then, if that first type of therapy is not successful, can automatically administer other types of electrical therapy.

Multi-mode therapy, including cardioversion, has proven to be an essential feature in modern-day implantable cardioverter defibrillators, or "ICDs." Even though devices may not always be programmed for multi-mode therapy, it is essential to physicians that all ICDs have the capability to be so programmed. It is for that reason that every ICD device sold in the United States during the relevant

period was capable of administering multi-mode therapy in which one of the therapies was cardioversion.

The complaint was filed in November 1996. Jurisdiction in the district court was based on 28 U.S.C. §1338 (and §1331). A first three week trial in June 2001 in the Indianapolis federal court included method claim 4 and apparatus claim 13. The jury found both non-infringed. Cardiac appealed with respect to method claim 4 but not with respect to apparatus claim 13. In August 2004, the Federal Circuit vacated the claim construction for method claim 4 as erroneous and remanded to the district court to retry infringement under the corrected claim construction. App. 102a.

In March 2006, the district court restricted Cardiac's damages on the basis of a new defense asserted by St. Jude which was available but not asserted in the 2001 trial. In doing so, the district court overruled Cardiac's assertions that (1) under applicable and controlling Seventh Circuit law as well as the law of the Federal Circuit, St. Jude waived this defense and (2) this restriction was contrary to applicable Federal Circuit damages law. App. 169a, 182a. Also in March 2006, the district court held that, under 35 U.S.C. §271(f), Cardiac could recover damages for products made here but sold abroad. App. 182a-188a.

In March 2007, the district court rendered summary judgment that claim 4 was invalid as anticipated by two prior art references which the Federal Circuit held in its 2004 decision did not

render claim 4 obvious. App. 136a-137a. The jury in its 2001 verdict concluded that St. Jude had not proved that claim 4 was obvious in view of these two references. However, the district court granted JMOL of obviousness as to these two references. The Federal Circuit in its 2004 decision reversed the district court's JMOL decision and reinstated the jury's verdict of non-obviousness. App. 93a.

In its 2008 decision, the Federal Circuit (1) reversed the district court's holding of invalidity of claim 4 based upon anticipation, (2) affirmed the district court's §271(f) holding, (3) affirmed the district court's holding permitting St. Jude upon remand to raise a new defense and (4) affirmed the district court's holding restricting Cardiac's damages. App. 80a.

In March 2009, the *en banc* Federal Circuit granted St. Jude's petition to rehear *en banc* the §271(f) issue. App. 57a-60a. In August 2009, the *en banc* Federal Circuit reversed the district court's §271(f) holding and decided the remaining issues as they had been previously decided in the panel's 2008 decision. App. 36a.

St. Jude's New Defense on Remand

St. Jude's new defense was that Cardiac could only prove infringement for those St. Jude devices that actually executed cardioversion during the infringement period, *i.e.*, those implanted devices actuated by the patient's deteriorating condition to deliver a cardioversion shock.

However, applicable and controlling Seventh Circuit law (on a procedural issue unrelated to patent law) precludes a new defense on remand previously available but not previously asserted. The Seventh Circuit has repeatedly held that, with respect to a specific remand for determination of particular issues, "[a] party cannot use *the accident of a remand* to raise in a second appeal an issue that he could just as well have raised in the first appeal because the remand did not affect it." *United States v. Parker*, 101 F.3d 527, 528 (7th Cir. 1996), emphasis added; *see also United States v. Husband*, 312 F.3d 247, 250 (7th Cir. 2002) ("[A]ny issue that could have been but was not raised on appeal is waived and thus not remanded."); *Ty, Inc. v. Publications Int'l Ltd.*, No. 99 C 5565, 2003 WL 21294667, *3-4 (N.D. Ill. June 4, 2003) (citing *Parker* and prohibiting an accused infringer from raising a defense that it "could just as well raised in the first appeal").

While the Seventh Circuit rule in *Parker* is directed to issues that a party failed to raise in a first appeal, the same rationale would apply to issues that a party failed to raise in the first trial. Here, St. Jude's new damages defense could have been raised in the first trial. Thus, not having raised this defense in the first trial, St. Jude may not use "the accident of a remand" to now raise this defense.

Further, the Federal Circuit precluded a new damages argument offered for the first time on remand in *Tronzo v. Biomet, Inc.*, 236 F.3d 1342, 1347 (Fed. Cir. 2001). In *Tronzo*, the jury awarded

Tronzo certain compensatory damages. On appeal, the Federal Circuit reversed and remanded for a new determination of damages "because the compensatory damages were computed incorrectly." *Id.* at 1345. On remand, Tronzo offered a new argument (the "wrongdoer rule") to support the jury award of compensatory damages. *Id.* at 1347. But the district court refused to entertain this argument since it was offered for the first time on remand. *Id.*

On appeal, the Federal Circuit agreed with the district court, holding that "Dr. Tronzo made strategic decisions in the initial trial concerning what evidence and arguments to advance in support of his theory of damages. We see no error, therefore, in the district court's refusal to address a new theory presented for the first time on remand." *Id.* Similarly, here, St. Jude made strategic decisions in the first trial as to which defenses to assert and it should be precluded from asserting its new cardioversion damages defense for the first time on remand.

Nonetheless, the Federal Circuit held against Cardiac, a holding that unless reversed by this Court is likely to be cited for the proposition that on remand a party can raise additional defenses that were not but could have been presented and disposed of on the first trial and appeal.

Damages for Infringement

The capability to practice the claimed invention was essential to St. Jude's ability to sell the accused ICDs, regardless of whether they were ultimately

programmed to do so. A company would not market and a physician would not implant an ICD without such a capability. Where, as here, the capability to practice the claimed invention is critical to the infringer's sales of its accused products, the Federal Circuit has expressly held it appropriate for the patentee to recover damages based on all of those sales, regardless of whether all such sales led to infringement.

Stryker Corp. v. Intermedics Orthopedics, Inc., 96 F.3d 1409 (Fed. Cir. 1996) is instructive. Stryker accused Intermedics of infringing a patent directed to a femoral prosthesis. *Id.* at 1412. The accused "APR II" product could be installed either with or without a distal sleeve. *Id.* When installed with the sleeve, it infringed, but when installed without the sleeve, it did not. *Id.* at 1413. Intermedics sold 20,966 APR II stems, but only 4,718 sleeves. Therefore, more than 16,000 of the approximately 21,000 APR II sales (78%) did not result in infringement. *Id.* at 1416.

The Federal Circuit nevertheless held that Stryker was entitled to collect damages on all of Intermedics APR II sales, regardless of whether infringement actually occurred in each use. As the Federal Circuit explained:

> Intermedics always manufactured the APR II with a sleeve option. The APR II was marketed as a total system, including the distal sleeves. . . . The sales agent would attempt to sell the entire APR II system to a surgeon. In most circumstances, the final decision of

> whether or not to install the APR II with the distal sleeve was made in surgery. . . . An orthopedic surgeon also testified that the entire system -- the APR II and its distal sleeve -- would be available in the operating room for the surgeon to implant.

Id. at 1416-17 (internal citations omitted).

Because the capability of the APR II to be installed with a sleeve in appropriate circumstances was an important factor in physicians' decisions to purchase the products, the Federal Circuit held that Stryker was entitled to collect lost profits for all of Intermedic's sales, even though only a small percentage of them actually resulted in infringement. As the Federal Circuit explained:

> [We] find no error in the district court's decision to award damages for all APR II sales. It can properly be said that appellants damaged appellees each time they supplied an APR II system, complete with a distal sleeve, to a surgeon. Once the APR II system was supplied to a surgeon, [plaintiff] lost the opportunity to make the sale. It does not matter if the surgeon installed the APR II stem without the distal sleeve because the compensable injury had already occurred -- when the APR II was supplied to the surgeon instead of the Omniflex. *Put another way, by supplying the APR II to surgeons,*

> *appellants kept the Omniflex out of the operating room.*

Id. at 1417 (emphasis added).

The facts here are strikingly similar. All of St. Jude's ICDs are capable of practicing the claimed method, and this capability is extremely important to physicians. Physicians make the decision as to whether to activate the infringing multi-mode feature on a patient-by-patient basis, but St. Jude could not have sold its ICDs in the first place if they did not have the claimed multi-mode capability. Thus, as in *Stryker*, by supplying the accused ICDs to surgeons, St. Jude kept Cardiac "out of the operating room."

The district court (and later the Federal Circuit) distinguished *Stryker* on the basis that it involved an apparatus claim rather than a method claim.

> The basis for the *Stryker* court's decision was its recognition that Stryker was damaged by the defendant "each time [Intermedics] supplied an APR II system, complete with a distal sleeve, to a surgeon." *Id.* at 1417. That is, the apparatus patent was directly infringed by each sale of the device, whether it was used or not.

App. 181a.

However, contrary to the district court's (and later the Federal Circuit's) assumption, the apparatus claim in the Stryker patent was not

"directly infringed by each sale of the device, whether it was used or not." The claim required that the sleeve be "integral" with the stem ("a distal tip [sleeve] integral with the distal end of the stem," *Stryker*, 96 F.3d at 1412) and the sleeve was only "integral" with the stem when the surgeon chose to implant the sleeve.

> The sales agent would attempt to sell the entire APR II system to a surgeon. In most circumstances, the final decision of whether or not to install the APR II with the distal sleeve was made in surgery. Because of the timing of this decision, the surgeon needed the entire system in the operating room and a responsible APR II sales agent would make sure that the sleeves were available in the operating room for the surgeon.

Id. at 1416-17 (internal citations omitted). The sleeves and stems must have been sold separately since 20,966 stems but only 4,718 sleeves were sold. *Id.* at 1412.

Therefore, Cardiac should have been entitled to damages for all of St. Jude's accused ICD sales, regardless of how often they were actually programmed to cardiovert.

Nonetheless, the Federal Circuit held against Cardiac, a holding that unless reversed by this Court is likely to be cited for the proposition that even though the value of a method invention is its

availability for use if needed, damages for infringement are restricted to actual use.

Foreign Sales (§271(f))

For there to be literal infringement of a machine patent, the claim must read on the accused machine. A machine may be a number of parts connected together to perform a particular function. Prior to the enactment of 35 U.S.C. §271(f) in 1984, a manufacturer could make the machine here, sell it abroad, avoid liability by not assembling the machine here and, instead, ship the unassembled parts with assembly instructions to a customer in a foreign country.

In *Laitram Corp. v. Deepsouth Packing Co.*, 443 F.2d 936 (5th Cir. 1971), a patent infringement action involving a shrimp deveiner machine, the Fifth Circuit had to decide

> whether Deepsouth may sell its infringing machine in foreign markets when it produces all essential parts of the machine in the United States but ships it in a form which contemplates minor final assembly in such foreign markets. We hold it may not.

Id. at 937.

However, this Court reversed, holding that

> In sum: the case and statutory law resolves this case against the respondent. When so many courts have

> so often held what appears so evident -- a combination patent can be infringed only by combination -- we are not prepared to break the mold and begin anew.

Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 532 (1972).

Congress thought the law ought to be otherwise and, having the power of the last word, enacted §271(f) to overrule *Deepsouth*. In doing so, Congress did not restrict §271(f) to machine patents but, instead, made it applicable to any "patented invention." §271(f)(1) and (2) provide

> (1) Whoever without authority supplies or causes to be supplied in or from the United States *all or a substantial portion of the components of a patented invention*, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
>
> (2) Whoever without authority supplies or causes to be supplied in or from the United States *any component of a patented invention* that is especially made or especially adapted for use in

> the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Public Law 108-173, sec. 1101(d), 117 Stat. 2457 (Dec. 8, 2003), emphasis added.

The term "invention" is defined in 35 U.S.C. §100 to mean "invention or discovery." The four classes of patentable invention are set forth in 35 U.S.C. §101 as (1) "process," (2) "machine," (3) "manufacture" and (4) "composition of matter." The Congressional intent in not limiting §271(f) to the *Deepsouth* "machine" was to overrule *Deepsouth* as to each of the four classes of invention.

The Federal Circuit so stated in March 2005 in *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005), holding that "every form of invention eligible for patenting falls within the protection of section 271(f)" and "deserves the protection of section 271(f)." *Id.* at 1339.

Later that year in October, the Federal Circuit specifically held that the "process" or "method" class of invention was included in §271(f). *Union Carbide*

Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), holding that "*every* component of *every* form of invention deserves the protection of 35 U.S.C. § 271(f)" and "because § 271(f) governs method/process inventions, Shell's exportation of catalysts [for use in the patented process] may result in liability under § 271(f)." *Id.* at 1379-80, emphasis by Federal Circuit. A petition for rehearing *en banc* was denied with four judges dissenting. *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 434 F.3d 1357 (Fed. Cir. 2006).

In April 2007, this Court decided a §271(f) case but specifically left for another day the issue whether "an intangible method or process" can qualify as a "patented invention" under §271(f). *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 452, n.13 (2007).

As noted above, in this case, the district court held that §271(f) includes process inventions, a Federal Circuit panel affirmed but the *en banc* Federal Circuit held by an 11-1 vote that §271(f) excluded process inventions.

The primary basis for the *en banc* decision appears to be the actual language of §271(f). Although noting that "the isolated 'patented invention' language in Section 271(f) by itself might seem to extend to all inventions within the definition of 'invention,'" the *en banc* court found otherwise, holding that "we cannot disregard all the other language of that section, which, as we shall demonstrate, makes it clear that it does not extend to method patents." App. 27a.

According to the Federal Circuit, since the §271(f) statutory language requires that unassembled "components of a patented invention" be shipped abroad, since components of a process are "acts or steps" and since "acts or steps" cannot be shipped abroad, Congress must have intended without saying so to exclude process inventions from the ambit of §271(f)'s "patented invention."

However, if Congress wanted to exclude process inventions from §271(f)'s ambit, it would have said so rather than resorting to a highly cryptic use of the word "components." Further, contrary to the Federal Circuit's strained conclusion, there is no logical difficulty in concluding that Congress viewed the components of a patented method as the apparatus or materials necessary to practice the method. It would be difficult to deny that the element most necessary to the practice of the patented process is the ICD. Also, the purpose of §271(f) was to overrule *Deepsouth* as to all classes of invention, not to leave a process loophole unplugged.

REASONS FOR GRANTING THE PETITION

St. Jude's New Defense Should Not Have Been Permitted

The Federal Circuit held that St. Jude had not waived its defense to limit damages because, supposedly, there was no incentive for St. Jude to assert this defense at the first trial.

> The jury was presented with a damages decision regarding two claims of the

> '288 patent: an apparatus claim that has since been abandoned by Cardiac and the method claim (claim 4) that is at issue on appeal. While both patent claims were at issue during trial, St. Jude would not have benefited if it had moved to limit damages because the damages on the apparatus claims would have covered any sale of an apparatus that *could* execute the elements of the claims. However, now only a method claim is at issue; thus, St. Jude stands to benefit from limiting damages to devices that actually practice the method. As the district court noted, the purpose of the waiver rule is to prevent a party from arguing on remand what it should have argued at trial or on appeal. Citation omitted. St. Jude cannot have been expected to raise at trial an argument that would not have reduced damages until after Cardiac abandoned its apparatus claim on remand.

App. 18a-19a, emphasis by Federal Circuit.

However, the Federal Circuit's reasoning fails to take into account that each claim in a patent must be considered separately and that the jury could have found claim 4 valid and infringed but claim 13 either invalid or not infringed. In such a case, St. Jude would have been restricted to the defenses it raised at trial with respect to claim 4 and could not raise a

new defense because liability was found for claim 4 and not for claim 13. Thus, contrary to the Federal Circuit's reasoning, St. Jude would have been expected to assert its new defense at trial since it had no assurance that claim 13 would not be held invalid or not infringed.

Also contrary to the Federal Circuit's reasoning, had liability not been established for claim 13 but established for claim 4 and if St. Jude's new defense would reduce damages as St. Jude now asserts, there was unquestionable incentive for St. Jude to assert its new defense at the 2001 trial. Thus, St. Jude should not have been permitted to use the "accident of a remand" to assert a new defense which it should have raised earlier.

Since the Value of the Invention Was Its Availability for Use If Needed, Damages Should Not Have Been Restricted to Actual Use

In *Stryker*, as noted *supra*, the Federal Circuit held that Stryker was entitled to collect damages on all sales regardless of whether infringement occurred in each use. The Federal Circuit's decision appears to agree - "Cardiac disputes the district court's ruling by pointing this court to *Stryker*, in which we affirmed a district court's decision awarding damages on sales of an infringing prosthesis, *even in cases in which a distal sleeve, a required element of the claim, was not included. See Stryker*, 96 F.3d at 1416-17." App. 19a, emphasis added.

The Federal Circuit states that "*Stryker* is distinguishable from this case by the type of

damages being sought and the type of patent being asserted," noting that *Stryker* involved an apparatus claim and lost profits whereas this case involves a method claim and a reasonable royalty. *Id.*

As to this supposed apparatus/method claim distinction, there is no difference in this case since the apparatus claim in *Stryker* required that the sleeve be "integral" with the stem ("a distal tip [sleeve] integral with the distal end of the stem," *Stryker*, 96 F.3d at 1412) and the sleeve was only "integral" with the stem when the surgeon chose to join them. There is little difference between an apparatus limitation that the sleeve is integral with the stem and a method limitation that the sleeve is joined to the stem to make it integral therewith. *See Quanta, supra*, holding that "[a]pparatus and method claims 'may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus'" and "methods nonetheless may be 'embodied' in a product." 128 S.Ct. at 2117-18.

Further, as is apparent, there would be no separate act of infringement in *Stryker* unless the sleeve was integral with the stem yet damages were awarded because the surgeon had the capability of joining the sleeve with the stem in the operating room. Likewise, in this case, the implanted stimulator has the capability of performing cardioversion should the patient's condition require it.

Also, even though *Stryker* concerned an apparatus claim, the accused infringer's ability to

sell the device turned on the availability of the sleeve (distal tip). 96 F.3d at 1416-17. Similarly, here, St. Jude's ability to sell its devices turns on the availability of cardioversion. Like method claims, apparatus claims generally have to be infringed to warrant damages, but in *Stryker*, as here, because the market for the device *depended* on the infringing capabilities, the Federal Circuit did not limit damages to those devices that infringed. *Stryker*, 96 F.3d at 1417.

Likewise, as to the supposed lost profits/reasonable royalty distinction, there is no meaningful difference in this case. The Federal Circuit decision states

> In the present case, however, Cardiac is not seeking lost profits on an apparatus and therefore cannot rely on the reasoning in *Stryker*. Here, Cardiac seeks royalties on its patented method. "A method claim is directly infringed only by one practicing the patented method." *Joy Tech v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993). Thus, regarding claim 4 of the '288 patent, infringement can only occur in cases which the patented method is practiced.

App. 20a.

However, that *Stryker* concerned lost profits instead of a reasonable royalty is a distinction without a difference. In this case, royalties, like lost profits, would not depend on the actual execution of

every step of the claimed method but would instead depend on the ability of the device to execute the method. That is, a licensee would pay a royalty on the number of devices sold (or a patentee would lose profits for infringing sales of those devices), not on the number of devices that perform the therapy when implanted in a patient.

Thus, as shown in *Stryker*, when the capability to practice the claimed invention is critical to the infringer's sales, a patentee is eligible for damages on all sales, regardless of whether those sales led to infringement. Here, the ability to practice the claimed method is critical for St. Jude to even sell its devices at all.

The Maker of a Product Capable of Performing a Patented Method Should Be Liable for Products Made Here But Sold Abroad (§271(f))

In October 2005, a unanimous Federal Circuit panel held that §271(f) included method inventions. *Union Carbide*, *supra*. In January 2006, a petition for rehearing *en banc* was denied (with four judges dissenting). Yet, in August 2009, less than four years later, the Federal Circuit by an overwhelming margin (11-1) held that §271(f) does not include method inventions.

During this less than four year period, the language of §271(f) did not change and the issue here is only one of statutory construction. The only intervening event of record (for St. Jude) is this Court's decision in *Microsoft, supra,* but this Court specifically left for another day the issue whether "an

intangible method or process" can qualify as a "patented invention" under §271(f). *Id.* at 452, n.13. Although this Court in *Microsoft* spoke of the presumption against extraterritoriality, the Federal Circuit in its decision gives this presumption little emphasis, regarding it as a resolver of "[a]ny ambiguity." App. 34a. Although there is one other intervening event, this Court's *Quanta* decision, this event favors Cardiac, not St. Jude. Accordingly, the reason for the Federal Circuit's reversal of its position in a less than four year period is not clear.

The lone dissenter, Judge Newman, devotes far more attention to this issue than her colleagues and presents a compelling, even overwhelming case that Congress did not intend to exclude process inventions from the ambit of the "patented invention" recited in §271(f). Judge Newman explains that "[t]he court's interpretation of §271(f) to exclude all process inventions is contrary to the text of the statute, ignores the legislative history, is without support in precedent, and defeats the statutory purpose." App. 38a.

Judge Newman points out that (1) the statute is unambiguous, (2) many sections of title 35 use the terms "invention" or "patented invention" or "patentable invention" when referring to all of the statutory classes of invention and (3) when a specific class of invention is intended, it is explicitly stated and §271(f) states no such limitation. As Judge Newman puts it, her colleagues' statutory interpretation is an "extreme redefinition." App. 38a-40a.

Judge Newman further notes that this Court has stressed that

> in interpreting a statute a court should always turn first to one, cardinal canon before all others. We have stated time and again that courts must presume that *a legislature says in a statute what it means and means in a statute what it says there. Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-254 (1992).

App. 40a-41a, emphasis added, and that this Court in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) "addressed the term 'patented invention' as it appears in §271(e), an infringement provision enacted six weeks before §271(f)," App. 41a, and

> rejected the argument that the term "patented invention" in §271(e) was limited by other language in the provision to mean only drug patents, *holding that "[t]he phrase 'patented invention' in §271(e)(1) is defined to include all inventions*, not drug-related inventions alone." *Id.* at 665.

Id., emphasis added.

This Court's holding in *Eli Lilly* is as applicable to this case as it was to that case - "[I]f the statute had been intended to apply only to drug-related inventions, 'there were available such *infinitely more clear and simple ways of expressing that intent* that it is hard to believe the convoluted manner petitioner

suggests was employed would have been selected.' *Id.* at 667." *Id.*, emphasis added. Similarly in this case, if the statute had been intended to exclude process inventions, there were available infinitely more clear and simple ways of expressing that intent.

Also plainly inconsistent with the Federal Circuit's conclusion is the overriding purpose of §271(f) to plug the *Deepsouth* statutory loophole. As articulated by Judge Newman, "[d]espite the clarity of 'patented invention' in §271(f), and the context of concern for statutory loopholes inimical to the interest of innovators in the United States, this court now rules that the legislators intended to preserve a large loophole for patented processes, and never intended to cover more than the narrow *Deepsouth* loophole for machinery." App. 49a. As Judge Learned Hand so succinctly stated (as quoted by Judge Newman), "statutes always have some purpose or object to accomplish." App. 55a.

In the end analysis, it is simply much too great a leap to conclude that the words "component" and "supply" defeat the plain text of §271(f). Again, as articulated by Judge Newman,

> On the established understanding of how processes are performed, it cannot be ruled that the words "component" and "supply" in §271(f)(1) *impart a unique meaning that defeats the plain text of the statute.* It cannot be ruled that Congress, along with all of the contributors to this legislation, who

> understood and intended the use of general terms to embrace all forms of patented invention in Title 35, *nonetheless silently eliminated patented processes from "patented invention" in §271(f).*

App. 53a, emphasis added.

Judge Newman concludes that her colleagues failed to consider the extensive legislative record or the consequences of negating the legislative purpose.

> The court's ruling reopens, for process inventions, the loophole that was plugged by §271(f) for all patented inventions. The extensive legislative record shows consideration of equity, economics, innovation incentive, and international concerns, in the evolution of the text of §271(f). The *en banc* court makes no mention of any of these concerns, and does not discuss the consequences of today's holding in negating the legislative purpose. I respectfully dissent from the court's statutory interpretation and the decision based thereon.

App. 56a.

CONCLUSION

For the foregoing reasons, Cardiac's petition should be granted.

Respectfully submitted,

ARTHUR I. NEUSTADT
Counsel of Record
BARRY J. HERMAN
OBLON, SPIVAK, MCCLELLAND
MAIER & NEUSTADT, L.L.P.
1940 Duke Street
Alexandria, Virginia 22314

SIDNEY J. SILVER
SILVER, FREEDMAN & TAFF, L.L.P.
3299 K Street, N.W., Suite 100
Washington, D.C. 20007
(202) 295-4500

Counsel for Petitioners
Mirowski Family Ventures, LLC
and Anna Mirowski

J. MICHAEL JAKES
KARA F. STOLL
MICHAEL V. O'SHAUGHNESSY
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, D.C. 20001

Counsel for Petitioners
Cardiac Pacemakers, Inc. and
Guidant Sales Corporation

November 17, 2009

APPENDIX

Appendix A

United States Court of Appeals for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC. and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and ANNA MIROWSKI,

Plaintiffs-Appellants,

v.

ST. JUDE MEDICAL, INC., and PACESETTER, INC.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the Southern District of Indiana in 96-CV-1718, Judge David F. Hamilton.

DECIDED: August 19, 2009

Before NEWMAN, MAYER, and LOURIE, Circuit Judges. Opinion for the court filed by Circuit Judge

LOURIE, in which Circuit Judge MAYER joins and Circuit Judge NEWMAN joins parts A, B, C.1, and D.

Part C.2 was heard en banc before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges. Opinion for the court filed by Circuit Judge LOURIE, in which Chief Judge MICHEL and Circuit Judges MAYER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE join. Dissenting opinion filed by Circuit Judge NEWMAN.

LOURIE, Circuit Judge.

Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively, "Cardiac" or "appellants") appeal from the decision of the United States District Court for the Southern District of Indiana granting summary judgment of invalidity of claim 4 of U.S. Patent 4,407,288 ("the '288 patent"). See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 483 F. Supp. 2d 734 (S.D. Ind. 2007) ("Invalidity Decision"). Cardiac also appeals aspects of the district court's decision concerning damages. See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 418 F. Supp. 2d 1021, 1027-30 (S.D. Ind. 2006) ("Damages Decision"). Because the district court erred in concluding in light of our prior mandates that it could find the '288 patent anticipated, we reverse on invalidity. In light of the fact that infringement has already been decided by the district court, we remand the case solely for a determination of damages. We affirm the court's decision limiting damages to those

devices that can be shown to have executed the steps of claim 4 of the '288 patent.

St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St. Jude") cross-appeal from the district court's decision permitting damages under 35 U.S.C. § 271(f). See Id. at 1027-30. The en banc court reverses the district court's determination that 35 U.S.C. § 271(f) applies to method claims and hence permits damages in this case on devices exported where the claimed method is carried out in countries other than the United States (see Section C.2 of this opinion).

BACKGROUND

This patent dispute concerning implantable cardioverter defibrillators ("ICDs"), has been before us on four previous occasions. See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 296 F.3d 1106 (Fed. Cir. 2002); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 381 F.3d 1371 (Fed. Cir. 2004) ("2004 Opinion"); Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 144 F. App'x 106 (Fed. Cir. 2005) ("2005 Reassignment Order"); In re Cardiac Pacemakers, Inc., 183 F. App'x 967 (Fed. Cir. 2006) ("2006 Writ Order"). Three of our prior decisions, the 2004 Opinion, the 2005 Reassignment Order, and the 2006 Writ Order, are relevant to this appeal.

ICDs are small devices that detect and correct abnormal heart rhythms that can be fatal if left untreated. The ICDs in this case work by administering electrical shocks to the heart, those shocks being calibrated to restore normal heart

functioning. Implantable cardiac devices can be programmed to administer different types of electrical shocks, including pacing shocks (which are relatively low power shocks), defibrillation (relatively high power shocks), and cardioversion, the definition of which has been a source of dispute throughout the protracted litigation of this case.

Cardiac owns various patents relating to cardiac defibrillators, including the '288 patent. The '288 patent claims a method of heart stimulation using an implantable heart stimulator that is capable of detecting heart arrhythmias, or irregular heart rhythms, and of being programmed to treat the arrhythmia through either single or multimode operation. Multimode operation allows a heart stimulator to respond to arrhythmias by applying first one type of shock and then, if unsuccessful, administering a second type of shock. Claim 4 of the '288 patent, the only claim at issue on appeal, is dependent on claim 1:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising:
>
> (a) determining a heart condition of the heart from among a plurality of conditions of the heart;
> (b) selecting at least one mode of operation of the implantable heart stimulator

which operation includes a unique sequence of events corresponding to said determined condition;

(c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

* * *

4. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.

The litigation history of this case is complicated and protracted, but for clarity's sake we will recite the portion of that history that is relevant to this appeal. Cardiac brought an infringement action against St. Jude on November 26, 1996, accusing St. Jude of selling ICDs that infringed a number of Cardiac's patents. In 2001 the case was tried before a jury. The jury returned a verdict awarding Cardiac $140 million in royalties for infringement of U.S. Patent 4,316,472 ("the '472 patent"). Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., No. IP-96-1718-C, 2002 U.S Dist. LEXIS 14767, at *7 (S.D. Ind. July 5, 2002). The jury found the '288 patent valid and enforceable, but not infringed by St. Jude's ICDs. Id. at *6-*7. In doing so, the jury rejected St. Jude's argument that the invention of the '288 patent was obvious in light of various prior art references, including U.S. Patent 3,805,795 ("Denniston") and United Kingdom Patent Application 2,026,870 ("Duggan"). Id. at *117, *120. The jury also rejected St. Jude's argument that the '288 patent was

unenforceable for inequitable conduct.[1] Id. at *7.

Following the trial, the district court granted several post-verdict motions that overturned the jury verdict and conditionally granted a new trial on several issues that St. Jude had lost at trial. First, the court granted St. Jude judgment as a matter of law ("JMOL") on invalidity and noninfringement of the '472 patent, thereby vacating the jury's $140 million damage award. Id. at *100. Cardiac has not appealed any of the district court's decisions regarding the '472 patent.

Regarding the '288 patent, which the jury found valid and not infringed, the district court granted St. Jude's JMOL motions for invalidity due to obviousness and lack of best mode. Id. at *100-*133. The court denied St. Jude's JMOL motion of unenforceability, in which St. Jude alleged that Cardiac had failed to pay proper maintenance fees. Id. at *133-*143. Finally, the court further denied Cardiac's motion for a new trial on infringement. Id. at *195-*196. The court granted a conditional new trial on the obviousness issue and the inequitable conduct issue in the event that the JMOL decision finding the '288 patent obvious was reversed on appeal. Id. at *114, *143.

Following the district court's post-trial decisions, Cardiac appealed the district court's grant of St.

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[1] The jury also rejected St. Jude's argument that the '288 patent failed to comply with the best mode requirement of 35 U.S.C. § 112 ¶ 1. St. Jude has not appealed any decisions relating to 35 U.S.C. § 112.

Jude's motion for JMOL of invalidity of the '288 patent as well as the court's rejection of Cardiac's motion for JMOL of infringement of claim 4 of the '288 patent. On appeal, we reversed on both issues. 2004 Opinion, 381 F.3d at 1378-80. Regarding validity, we held that there was "substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion," and therefore reinstated the jury verdict that the "'288 patent is not invalid for obviousness. Id. We also found that the district court's conditional grant of a new trial on obviousness "exceeded the court's discretionary authority." Id. at 1380.

Regarding infringement, we reversed the court's claim construction and therefore vacated the jury's finding of noninfringement. We held that the district court had erred in finding that the "determining" step of claim 4 was a "step-plus-function" limitation under 35 U.S.C. § 112 ¶ 6 and remanded the case to the district court to modify its claim construction of the "determining" step in accordance with our opinion. Id. at 1382. Lastly, we agreed with St. Jude that our reversal of the district court's claim construction entitled St. Jude to a "jury determination on the question of infringement." Id. at 1383. We summarized our holding as follows:

> We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial on infringement and reassessment of damages.

Id. at 1374.

On remand, the case was returned to Judge Hamilton. Cardiac challenged that assignment, claiming that Seventh Circuit Rule 36 required automatic reassignment of a case remanded for a new trial to a new judge. Judge Hamilton ultimately agreed with Cardiac to reassign the case to another judge. He then certified the issue for an interlocutory appeal. St. Jude appealed the reassignment decision to this court, and we reversed, finding that further assignment to Judge Hamilton would best conserve judicial resources. 2005 Reassignment Order, 144 F. App'x at 106. We also noted that the case had been remanded for "a new trial on literal infringement of one claim of one patent and for any damages determination." Id. at 107.

With that background in mind, we now turn to the decisions of the district court that are at issue on appeal. After that remand, both sides submitted to the district court proposed claim constructions for the disputed "determining" limitation in claim 4 of the '288 patent, and the district court adopted Cardiac's definition of "determining" with one minor change (which is not challenged on appeal). Damages Decision, 418 F. Supp. 2d at 1027-30. Cardiac also moved for summary judgment on St. Jude's invalidity and unenforceability defenses, arguing that such defenses were precluded by our 2004 Opinion and the mandate rule. Id. at 1031. The district court disagreed and denied the motion. The court found that "[t]he Federal Circuit's remand left open the possibility of new invalidity and unenforceability defenses." Id. at 1031. According to the district

court, while our 2004 Opinion precluded assertion of the same obviousness argument that St. Jude had raised and lost previously, "St. Jude's other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand." Id. at 1032. In arriving at that conclusion, the district court relied on three points. First, the court found that our remand instructions in the 2004 Opinion "suggested" that a new claim construction might give rise to new invalidity defenses, particularly with regard to the adequacy of the written description requirement. Id. Second, the court found that because St. Jude had no obligation on appeal to present alternative arguments for invalidity, those alternative arguments were not precluded on remand. Id. at 1032-33. Third, and most importantly, the court found that St. Jude did not abandon or waive its invalidity defenses that became relevant only on remand; in other words, due to the court's new claim construction of "determining," certain prior art that was not invalidating under the erroneous claim construction may have become invalidating under the new claim construction. Id. at 1033.

The district court also rejected Cardiac's motion for summary judgment on St. Jude's affirmative defense of inequitable conduct. The court found that "all of St. Jude's arguments concerning unenforceability" could be asserted on remand. Id. The district court found that this court's mandate "did not even suggest, let alone require," that the issue of inequitable conduct be precluded from adjudication on remand. Id. at 1034.

Finally, the district court granted in part and denied in part St. Jude's motion for summary judgment limiting damages. The court granted St. Jude's motion to limit damages to ICDs that actually performed the claimed steps. Id. at 1040. The court held that because claim 4 is a method claim, only those devices that "can be shown to have executed" the claimed method were to be used in the damages calculation. Id. at 1042. However, the court rejected St. Jude's motion to limit damages to U.S. sales of ICDs. The court held that, according to Federal Circuit case law regarding 35 U.S.C. § 271(f), Cardiac's potential damages included the sale of infringing devices supplied from the United States to other countries. Id. at 1042-44.

Following the district court's rulings on claim construction and the various summary judgment motions, Cardiac petitioned this court for a writ of mandamus directing the district court to vacate its order allowing St. Jude to assert invalidity and inequitable conduct defenses. We denied the petition. In doing so, we stated:

> [W]e repeat that we "remand[ed] for a new trial of infringement and reassessment of damages," including re-construction by the district court of the "determining" provision in light of our ruling that section 112 ¶ 6 did not apply. We also recognized that a new claim construction may raise directly related new issues, "such as whether the now-asserted scope of the claims is supported by the specification."

> All of the other issues on remand were finally decided, and are not subject to reopening on remand.

2006 Writ Order, 183 F. App'x at 967 (citations omitted) (emphasis added). The case was once more remanded to the district court.

On March 26, 2007, the district court granted Cardiac's motion for summary judgment of infringement, while also granting St. Jude's motion for summary judgment of anticipation. Invalidity Decision, 483 F. Supp. 2d at 745. As a threshold matter, the district court found that because of the new, broader claim construction, the anticipation defense was, in the words of this court, a "directly related new issue," and therefore not precluded by our previous decisions. Id. at 738-39 (quoting 2006 Writ Order, 183 F. App'x at 967). The court then examined the prior art and found that the '288 patent was anticipated by two references that had been presented to the jury: Denniston and Duggan. Id. at 740-45. Final judgment of invalidity was entered by the district court.

Cardiac timely appealed and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment de novo, "applying the same criteria used by the district court in the first instance." Rothe Dev. Corp. v. Dep't of Defense, 545 F.3d 1023, 1035 (Fed. Cir. 2008) (quoting W.H. Scott Constr. Co. v. City of Jackson, 199 F.3d 206, 211 (5th Cir. 1999)).

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). We review the interpretation of our own mandates de novo. Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1382 (Fed. Cir. 1999).

A. Invalidity

On appeal, Cardiac argues that the district court erred in granting summary judgment of invalidity. Preliminarily, Cardiac argues that invalidity was not at issue on remand because the mandate rule precluded St. Jude's anticipation defense. Alternatively, Cardiac argues that if we find that anticipation was still at issue on remand, then we should also find that the district court erred in finding that no genuine issues of material fact existed as to whether Duggan and Denniston were anticipating references, particularly with respect to whether Duggan teaches cardioversion and whether Denniston teaches programming.

In response, St. Jude argues that while our 2004 Opinion and the mandate rule bar consideration of obviousness on remand, St. Jude is permitted to bring an anticipation defense. According to St. Jude, our reversal of the "determining" construction in the 2004 Opinion created new validity defenses due to the changed claim scope. St. Jude also claims that the '288 patent was anticipated by both Denniston and Duggan, as the district court found.

We agree with Cardiac that anticipation was not properly before the district court on remand. In the 2004 Opinion, we clearly stated that the purpose of the remand was "for a new trial of infringement and reassessment of damages." 2004 Opinion, 381 F.3d at 1374. Furthermore, we explicitly "reinstate[d] the jury verdict of validity." Id. The mandate rule requires that the district court follow an appellate decree as the law of the case. Sibbald v. United States, 37 U.S. 488, 492 (1838). Therefore, according to our explicit instructions, any new trial on remand was limited to an assessment of infringement and a calculation of any damages.

Of course, as St. Jude rightly notes throughout its brief, our 2004 Opinion altered the district court's claim construction, and in the 2006 Writ Order we left open the possibility that a new claim construction ruling "may raise directly related new issues." 2006 Writ Order, 183 F. App'x at 967. As one example of a directly related new issue, we suggested that written description may be challenged under a new, broader claim construction. Id. We did not explicitly include or exclude anticipation from the list of possible new issues raised by a new construction of "determining."

Thus, the question before us now is whether anticipation is a "directly related new issue" in this case, or whether our reinstatement of the jury's validity verdict precludes raising anticipation on remand. The jury found the claims of the '288 patent nonobvious in light of numerous prior art references, including both Duggan and Denniston. In overturning the jury's validity verdict, the district court permitted St. Jude to raise anticipation

arguments on remand that St. Jude did not raise at trial. The court based its decision on the fact that "St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial," due to the erroneous claim construction of "determining" used at trial. Damages Decision, 418 F. Supp. 2d at 1033. In finding the claims of the '288 patent nonobvious, the jury necessarily reached the conclusion that some element necessary to prove obviousness had not been demonstrated. For St. Jude to succeed in this appeal, that missing element would have to have been the "determining" limitation.

While it is true that a changed claim construction may permit new anticipation arguments, that cannot be the case here because the "determining" limitation never served as a basis for distinguishing the prior art from the '288 patent and is therefore not a "directly related new issue."

At trial, Cardiac did not dispute that the "determining" step was in the prior art and did not raise that step as a distinguishing feature between the '288 patent and Duggan or Denniston. See Reply Br. of Plaintiffs-Appellants at 12-14, 2004 Opinion (arguing that Duggan and Denniston do not teach cardioversion); Br. of Plaintiffs-Appellants at 21-24, 2004 Opinion (arguing that the jury heard evidence that the prior art did not teach "cardioversion," "multi-mode operation," and "programmability"); cf. id. at 22 (noting evidence that the Baker reference does not perform, among other things, the determining step). The evidence of obviousness during the trial primarily focused on whether the

prior art taught multi-mode with cardioversion. See Br. for Defendants-Cross Appellants at 7-8, 2004 Opinion (stating that with regard to obviousness, the only disputed limitations were the claimed invention's ability to perform multimode operation and the use of cardioversion). Duggan and Denniston were not only known to St. Jude before trial, but both references were presented to the jury. The jury found that those references did not invalidate the patent even though Cardiac did not dispute that the "determining" construction was known in the prior art. Thus, it cannot be said that the jury's decision hinged on the erroneous construction of that claim. Stated differently, the jury's verdict of validity could not have depended upon the erroneous construction of "determining" because it was uncontested during trial that that term was present in the prior art.

The initial, erroneous construction of "determining" was appealed by Cardiac in order to challenge the jury's verdict of noninfringement. While a change in claim construction often may affect a jury's validity determination, in this case it does not. Therefore, St. Jude cannot now be allowed to claim that its anticipation arguments involving Duggan and Denniston are "directly related" to the change in the construction of "determining," because the jury's validity determination, which we reinstated, did not depend upon that erroneous definition. Thus, in light of the jury's verdict and our previous mandates unique to this case, we reverse the district court's summary judgment of invalidity and reinstate the jury's verdict that the '288 patent has not been shown to be invalid.

B. Inequitable Conduct

Cardiac asks this court to instruct the district court that enforceability defenses are precluded from any remand order. According to Cardiac, the mandate rule requires such a determination. St. Jude counters that inequitable conduct is still at issue on remand because of the district court's explicit ruling that "in the event of a new trial . . . the inequitable conduct defense shall be part of the trial." Cardiac Pacemakers, 2002 U.S. Dist. LEXIS 14767, at *143. Because Cardiac failed to appeal that ruling, St. Jude contends, that decision is final.

The district court characterized St. Jude's inequitable conduct arguments as falling into three broad categories. The first category involved misrepresentations made before the PTO. Damages Decision, 418 F. Supp. 2d at 1033-34. Some of those arguments were raised by St. Jude at trial and rejected by the jury. Id. at 1034. Others were raised and abandoned at trial. Id. The second category of arguments involved three patents that are no longer at issue in this case. St. Jude alleges that those patents were asserted by Cardiac even though Cardiac knew that they were invalid. Id. The district court granted Cardiac's motion for summary judgment on those arguments, and St. Jude did not appeal that decision. Id.

We conclude that St. Jude has waived the first two categories of inequitable conduct arguments. St. Jude either failed to pursue those arguments at trial, thereby waiving the arguments, or failed to appeal the arguments to this court. Id. St. Jude cannot now

be heard to raise those arguments again on remand.

A third category of inequitable conduct arguments relates to misrepresentations made by Cardiac's expert, Dr. Bourland. The jury rejected many of St. Jude's inequitable conduct arguments based on Dr. Bourland's conduct, and the district court declined to reverse the jury's decision. However, due to revelations that came to light after trial, the court found that Dr. Bourland's conduct entitled St. Jude to a new trial. Cardiac Pacemakers, 2002 U.S. Dist. LEXIS 14767, at *143. In September 2006, the parties filed a stipulation stating that St. Jude would not pursue any defense based in whole or in part on Dr. Bourland's conduct. Following that stipulation, Cardiac filed a renewed motion for summary judgment on inequitable conduct. The district court never ruled on Cardiac's renewed motion because it entered a final judgment on anticipation on March 26, 2007.

With the stipulation removing Dr. Bourland's conduct as a basis for an inequitable conduct defense, St. Jude cannot now be heard to raise inequitable conduct on remand. Any language from the district court's opinion indicating otherwise would be an abuse of the court's discretion to grant a new trial. We therefore reinstate the jury's verdict of enforceability of the '288 patent and hold that enforceability should not form part of any new trial on remand.

C. Damages

Cardiac argues that the district court erred by

limiting damages to those ICDs that actually performed cardioversion during the infringement period. According to Cardiac, St. Jude waived its damages argument by not raising it at trial. Furthermore, Cardiac argues, Stryker Corp. v. Intermedics Orthopedics, Inc., 96 F.3d 1409 (Fed. Cir. 1996), and other cases have held that it is appropriate for patentees to recover damages based on sales of products with the mere capability to practice the invention.

St. Jude responds that it is not precluded from arguing for limited damages because the remanded damages assessment was significantly altered from the assessment that occurred at trial. Because Cardiac is now asserting only a method claim, St. Jude contends, any damages claim must be limited accordingly. Furthermore, in a cross-appeal, St. Jude argues that the district court erred in concluding that Cardiac could recover damages for overseas sales of St. Jude's ICDs under 35 U.S.C. § 271(f).

1. Damages Limited to Devices Performing Claimed Method

We agree with St. Jude that the district court correctly limited damages to those devices that were shown to infringe the '288 patent. As a preliminary matter, we find that St. Jude has not waived its argument to limit damages. The jury was presented with a damages decision regarding two claims of the '288 patent: an apparatus claim that has since been abandoned by Cardiac and the method claim (claim 4) that is at issue on appeal. While both patent claims were at issue during trial, St. Jude would not have

benefited if it had moved to limit damages because the damages on the apparatus claims would have covered any sale of an apparatus that could execute the elements of the claims. However, now only a method claim is at issue; thus, St. Jude stands to benefit from limiting damages to devices that actually practice the method. As the district court noted, the purpose of the waiver rule is to prevent a party from arguing on remand what it should have argued at trial or on appeal. Damages Decision, 418 F. Supp. 2d at 1035 (citing Tronzo v. Biomet, Inc., 236 F.3d 1342, 1347-48 (Fed. Cir. 2001)). St. Jude cannot have been expected to raise at trial an argument that would not have reduced damages until after Cardiac abandoned its apparatus claim on remand.

The district court was also correct in limiting damages to sales of ICDs that performed the steps of the claimed method. Cardiac disputes the district court's ruling by pointing this court to Stryker, in which we affirmed a district court's decision awarding damages on sales of an infringing prosthesis, even in cases in which a distal sleeve, a required element of the claim, was not included. See Stryker, 96 F.3d at 1416-17. The holding in Stryker is distinguishable from this case by the type of damages being sought and the type of patent being asserted. In Stryker, the patentee was seeking lost profits on an apparatus claim. We held, based on the particular facts of that case, that the patentee was entitled to profits on the sale of all devices, with or without the required distal sleeve because the sale of the device robbed the patentee of "the opportunity to make the sale." Id. at 1417. This was true because

the sleeve, while not included in every sale, was available to the surgeon during surgery. Id.

In the present case, however, Cardiac is not seeking lost profits on an apparatus and therefore cannot rely on the reasoning in Stryker. Here, Cardiac seeks royalties on its patented method. "A method claim is directly infringed only by one practicing the patented method." Joy Tech. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993). Thus, regarding claim 4 of the '288 patent, infringement can only occur in cases in which the patented method is practiced.

In Stryker, the court found that because the entire patented apparatus was "supplied" during surgery, the patent was infringed by any sale of the device. Stryker, 96 F.3d at 1416-17. In this case it cannot be said that St. Jude has somehow "supplied" all of the elements of Cardiac's patented method through its devices unless those devices actually performed all of the steps required by the claims. "The law is unequivocal that the sale of equipment to perform a process is not a sale of the process." Joy Tech., 6 F.3d at 773. Therefore, Cardiac can only receive infringement damages on those devices that actually performed the patented method during the relevant infringement period. We thus affirm the district court's ruling.

2. Section 271(f)

The court hears this section C(2) en banc. The district court, following our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil

Co., 425 F.3d 1366 (Fed. Cir. 2005), found that 35 U.S.C. § 271(f) applied to method claims and that St. Jude's shipment of ICDs abroad could result in a violation of that section. Damages Decision, 418 F. Supp. 2d at 1042-44. On cross-appeal to this court, St. Jude challenged the court's decision. The panel affirmed the court's decision on the basis of Union Carbide. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 303 F. App'x 884 (Fed. Cir. 2008). St. Jude filed a petition for rehearing en banc, which we granted, thus vacating the panel decision. Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., No. 07-1296, -1347, 2009 U.S. LEXIS 4379 (Mar. 6, 2009). The en banc court heard oral argument on this issue on May 29, 2009. For the reasons stated below, we reverse and hold that Section 271(f) does not cover method claims and is therefore not implicated in this case.[2]

a. Background on 35 U.S.C. § 271(f)

Before analyzing the merits of St. Jude's cross-appeal, some background on Section 271(f) is in order. In Deepsouth Packing Co., Inc. v. Laitram Corp., 406 U.S. 518 (1972), the Supreme Court held that a manufacturer who shipped unassembled parts of a patented shrimp deveining machine abroad was not liable for patent infringement. Because "it is not an infringement to make or use a patented product outside of the United States," the Court held that the shipment of unassembled components of the

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[2] The court has received a number of briefs amicus curiae on the Section 271(f) issue that we are reviewing en banc. The court is appreciative of these contributions.

deveining machine did not constitute patent infringement. Id. at 527, 531.

In response to Deepsouth, Congress enacted Section 271(f). See, e.g., Patent Law Amendments of 1984, S. Rep. No. 98-663, pp 2-3 (1984) (describing Section 271(f) as a response to the "Deepsouth decision which interpreted the patent law not to make it infringement where the final assembly and sale is abroad"); see also Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 444 & n.3 (2007) (AT&T II) (stating that Section 271(f) was enacted with Congress "[f]ocusing its attention on Deepsouth").

Section 271(f) provides in full as follows:

> (1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
>
> (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial

> noninfringing use, where such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f).[3]

This court first dealt with Section 271(f) in Standard Havens Products, Inc. v. Gencor Industries, Inc., 953 F.2d 1360 (Fed. Cir. 1991). Standard Havens involved patent claims directed to methods of producing asphalt compositions. Id. at 1363. We held simply that a "sale to a foreign customer" of an asphalt plant did not implicate the provisions of Section 271(f). Id. at 1372-74. Our opinion on that issue did not elaborate further.

We more fully addressed Section 271(f) in Eolas Technolgies, Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005). In that case, we held that Microsoft could not avoid Section 271(f) liability by exporting golden master disks containing software code that were subsequently copied onto computer hard drives and sold outside of the United States. Id. at 1331,

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[3] Our analysis here focuses on 271(f)(1), but is equally applicable to 271(f)(2). While the two paragraphs differ in some respects, neither party argues that the differences are relevant in this case. Indeed, both paragraphs require the "supply" of "components" that are capable of being "combined outside of the United States." Compare 35 U.S.C. § 271(f)(1) & (2); see also AT&T II, 550 U.S. 437, 454 n.16. The definition of those terms guides our analysis on this issue.

1341. Eolas involved both a product and a method claim. In holding that Microsoft was liable under Section 271(f), we held that the software code included on Microsoft's master disks was a "component" of a patented invention under Section 271(f), id. at 1339, and that the relevant "component" referred to a part of the product claim. See id. at 1339 (holding that the "computer readable code claimed in claim 6," the product claim, was "a part or component of that invention"). We rejected Microsoft's argument that the term "component" was limited to physical items, id. at 1340, and held that "section 271(f)'s 'components' include software code on golden master disks," id. at 1341. No specific mention was made in Eolas concerning the relationship between Section 271(f) and the method claims. See id. at 1339 (citing the patent specification, not the claims, as evidence that the patented invention was a software product).

Shortly after Eolas issued, we decided a similar issue in AT&T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005) (AT&T I). AT&T I involved a factual scenario similar to that in Eolas: Microsoft exported golden master disks containing software that was covered by a patent held by AT&T. The software, once shipped abroad, was copied onto hard drives and sold to foreign customers. In our holding in AT&T I, we relied on the holding in Eolas that intangible software code was capable of being a component of a patented invention. Id. at 1369. We further held that such software was "supplied" for purposes of Section 271(f) when "a single copy [was sent] abroad with the intent that it be replicated." Id. at 1370.

In the same year that we decided Eolas and AT&T I, we decided a third case dealing with the scope of Section 271(f). Our discussion of Section 271(f) in NTP, Inc. v. Research in Motion, Ltd. was limited to the question whether infringement liability was somehow proper under Section 271(f) where RIM supplied BlackBerry handheld devices to customers in the United States, and use of those devices (in concert with a relay of the Blackberry network located in Canada) would infringe NTP's patented method if all steps were performed in the United States. 418 F.3d. 1282, 1321 (Fed. Cir. 2005). We held that it was not. In doing so, we held that "[w]hile it is difficult to conceive of how one might supply or cause to be supplied . . . the steps of a patented method," the supply of BlackBerry devices to customers in the United States did not constitute the supply step required by Section 271(f). Id. at 1322.

In 2006, a panel of this court explicitly held that Section 271(f) applied to method claims. In Union Carbide, the court was presented with a case in which a catalyst, which was necessary to perform a patented method for producing ethylene oxide, was exported from the United States. 425 F.3d 1366, 1369 (Fed. Cir. 2006). The court held that Section 271(f) was applicable to the exportation of the catalyst and use of the patented method abroad. In doing so, the court referred to the catalyst as the "component" referred to in Section 271(f). It distinguished NTP by noting that the catalyst at issue in Union Carbide was directly supplied to foreign affiliates whereas the device in NTP was sold domestically and then used in a foreign country. Id.

at 1380. It found that Eolas, which supported a finding of infringement under Section 271(f), expressly under a product claim and impliedly under a method claim, was more factually analogous and earlier in time than NTP, and therefore governed the case. Id. Indeed, the court considered that the shipment of the chemical catalyst was an even stronger candidate for the application of Section 271(f) than the shipment of master disks in Eolas because, unlike Eolas, Shell used the shipped components directly in its process instead of using copies of the exported components. Id. at 1379. Thus, the court held that "because § 271(f) governs method/process inventions, Shell's exportation of catalysts may result in liability" under that section. Id. at 1380.

The Supreme Court subsequently examined Section 271(f) when it granted certiorari and reversed our decision in AT&T I. AT&T II, 550 U.S. 437 (2007). The Court held that Microsoft did not supply combinable components of a patented invention when it shipped master disks abroad to be copied. Because the foreign-made copies of Windows that were installed on computers were supplied "from places outside of the United States," the Court held that Microsoft had not supplied components from the United States. Id. at 452. The court reserved judgment on whether "an intangible method or process . . . qualifies as a 'patented invention' under § 271(f)," but noted that if so, the "combinable components of that invention might be intangible." Id. at n.13. The Court sent a clear message that the territorial limits of patents should not be lightly breached. Id. at 454-56.

b. Analysis

In construing the terms of Section 271(f), we do so "in accordance with [their] ordinary or natural meaning." Id. at 449 (alteration in original) (quoting FDIC v. Meyer, 510 U.S. 471, 476 (1994)). Section 271(f)(1) provides that one who "supplies . . . in or from the United States, all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components" shall be liable as an infringer. 35 U.S.C. § 271(f)(1). Section 271(f)(2) contains similar language.

Cardiac argues that the use of the term "patented invention" in 271(f) indicates Congress's intent to include all classes of invention within that statute's reach. Cardiac rightly notes that "invention" is defined in the U.S. Code to include "any new and useful process, machine, manufacture or composition of matter," 35 U.S.C. § 101, and thus is broad enough to include method patents. However, examination of the statute before us is not quite so simple. While the isolated "patented invention" language in Section 271(f) by itself might seem to extend to all inventions within the definition of "invention," we cannot disregard all the other language of that section, which, as we shall demonstrate, makes it clear that it does not extend to method patents. We also cannot ignore the context of the statute and its legislative history, which lead us to the same conclusion, which is that Section 271(f) does not encompass method patents.

In interpreting the terms of Section 271(f), it is critical to recall what a "patented invention" consists of when method patents are at issue. We have noted "the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps." In re Kollar, 286 F.3d 1326, 1332 (Fed. Cir. 2002); see also NTP, 418 F.3d at 1322 ("The invention recited in a method claim is the performance of the recited steps."). Thus, a component of a tangible product, device, or apparatus is a tangible part of the product, device, or apparatus, whereas a component of a method or process is a step in that method or process. As we demonstrate herein, this fundamental distinction between claims to a product, device, or apparatus on one hand and claims to a process or method on the other, is critical to the meaning of the statute and dooms Cardiac's argument on this issue.

Cardiac relies on the Supreme Court's language in Quanta Computer, Inc. v. LG Electronics, Inc., 128 S. Ct. 2109 (2008), in which the Court stated: "Apparatus and method claims may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus." Id. at 2118 (citation and internal quotations omitted). However, the Court's language throughout the Quanta opinion is focused on the similarities between method and apparatus patents in the unique context of patent exhaustion. See, e.g., id. at 2117-18 (noting that a method may be "embodied" in devices for purposes of a "sale"); id. (method patents may be "exhausted by the sale of an item"). Moreover, in an exhaustion context, which considers whether a patent owner has been fully compensated when a sale or

license of his invention has occurred, it matters little whether the patent involved claims to a product (apparatus) or a method. If a patent owner sells or licenses a product, it is not unreasonable to hold that the patent owner has received his due compensation under the patent, whether it is a product or a method patent. Thus, as the Supreme Court stated, for purposes of exhaustion, it may "be difficult to distinguish the process from the function of the apparatus." Quanta, 128 S. Ct. at 2118 (citation and internal quotations omitted). The Supreme Court's statement in an exhaustion context has no application here.

Our precedents draw a clear distinction between method and apparatus claims for purposes of infringement liability, which is what Section 271 is directed to. See, e.g., Joy Tech., 6 F.3d at 773-75 (stating that method claims are infringed only by practicing the steps of the method); NTP, 418 F.3d 1282, 1318 ("[A] patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized."). Section 271(f) "applies only to 'such components' as are combined to form the 'patented invention' at issue." AT&T II, 550 U.S. at 449 (footnote omitted). "Component" is defined as "a constituent part," "element," or "ingredient." Webster's Third New International Dictionary of the English Language 466 (1981); see also AT&T II, 550 U.S. at 449 n.11 (adopting same definition in Section 271(f) case). As we have seen, the patented invention at issue when a method patent is implicated consists of a "series of acts or steps." In re Kollar, 286 F.3d at 1332. The elements of a method are the steps that comprise the method. Thus, method patents do have

"components," viz., the steps that comprise the method, and thus they meet that definitional requirement of Section 271(f), but the steps are not the physical components used in performance of the method.

Cardiac disagrees that a component of a patented method is a step of that method. Instead, Cardiac urges us to adopt a definition of "component" that would encompass "the apparatus that performed the process." Appellants' Br. 15. That position is clearly contrary to the text of Section 271(f). It is not even supported by the lone amicus brief we have received in favor of including method patents within Section 271(f)'s reach. Br. for Ormco Corp. as Amicus Curiae Supporting Application of Section 271(f) to Method Claims, No. 07-1296,-1347 at 11 (Fed. Cir. Apr. 13, 2009) ("Ormco Br.") ("[T]he components of a method are the steps or acts that comprise the method.").[4]

Another subsection of Section 271 further undercuts Cardiac's proposed definition of "component." It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." Davis v. Mich. Dept. of Treasury, 489 U.S. 803, 809 (1989). Section 271(c) illustrates the contrasting treatment that Section 271 gives to tangible inventions and method inventions and the meaning of the term "component." Section

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[4] Aside from Ormco's brief, all other amicus briefs we have received support our conclusion that Section 271(f) does not apply to method patents.

271(c) contrasts "a component of a patented machine, manufacture, combination, or composition" with a "material or apparatus for use in practicing a patented process." 35 U.S.C. § 271(c). Congress clearly believed that a "component" was separate and distinct from a "material or apparatus for use in practicing a patented process." Thus, a material or apparatus for use in practicing a patented process is not a component of that process. The components of the process are the steps of the process.

Although such patented methods do have components, as indicated, Section 271(f) further requires that those components be "supplied." That requirement eliminates method patents from Section 271(f)'s reach. The ordinary meaning of "supply" is to "provide that which is required," or "to furnish with . . . supplies, provisions, or equipment." Webster's Third New International Dictionary of the English Language 2297 (1981). These meanings imply the transfer of a physical object. Supplying an intangible step is thus a physical impossibility, a position that not even Cardiac seems to dispute. See Appellants' Br. 15 (arguing that steps of a patented process, "which conceptually could not be supplied from the United States," were not the components of the process). As we have noted before, "it is difficult to conceive how one might supply or cause to be supplied all or a substantial portion of the steps in a patented method in the sense contemplated by" Section 271(f). NTP, 418 F.3d at 1322.

One amicus curiae brief has argued that one might supply a physical object that is the result of one of the steps of a patented process and combine

that object with the remaining steps abroad. Ormco Br. at 12-14. That argument, however, confuses the result of a method step with the step itself. See id. (arguing that one who "supplies the results of" patented steps meets the requirements of Section 271(f)) (emphasis added). Section 271(f) does not forbid the supplying of products that are the result of steps of the patented method; rather it forbids the supply of the components themselves. 35 U.S.C. § 271(f) (imposing liability on one who "supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention"). Thus, because one cannot supply the step of a method, Section 271(f) cannot apply to method or process patents.

Our holding today is fully consistent with the legislative history of Section 271(f). As discussed above, in enacting Section 271(f), Congress intended to overturn the holding in Deepsouth. AT&T II, 550 U.S. at 457-58. Deepsouth dealt with an apparatus patent, a shrimp deveining machine, and the exportation of the physical components of that machine. Deepsouth 406 U.S. at 519. Congress was clearly focused on closing the loophole presented in Deepsouth, viz., that shipping an unassembled patented product abroad for later assembly avoids patent infringement. Congress's focus on patented products is apparent from an examination of the legislative history. See, e.g., S. Rep. No. 98-663 at 6 (1984) (stating that Section 271(f) will "prevent copiers from avoiding U.S. patents by shipping overseas the components of a product patented in this country so that assembly of the components will be completed abroad." (emphasis added)); 130 Cong. Rec.

H10,525 (daily ed. Oct. 1 1984) (same). The legislative history of Section 271(f) is almost completely devoid of any reference to the protection of method patents and the Supreme Court has advised us that it is Congress's right, not the courts', to extend the statute beyond the Deepsouth problem it was designed to fix. See AT&T II, 550 U.S. at 457-58 (explaining that Congress designed 271(f) to close the Deepsouth loophole and that another loophole should be left in "Congress' court").

Cardiac argues that a single statement by former Commissioner of Patents, Donald Banner, indicates that Congress understood "components" to apply also to method patents. In a prepared statement, Mr. Banner stated that Section 271(f) "makes it infringement to supply components of a patented process for final assembly abroad, if supplied for the purpose of avoiding the patent." S. 1535 – A Bill To Amend Title 35, United States Code, To Increase The Effectiveness Of The Patent Laws And For Other Purposes: Hearing Before The Subcommittee On Patents, Copyrights And Trademarks of the Committee On The Judiciary, United States Senate, 98th Cong. 46 (1984) (prepared statement of Donald W. Banner, President, Intellectual Property Owners, Inc.). Cardiac argues that this statement proves that a method can have components, Appellants' Br. 17, a statement with which we do not disagree. What we do disagree with is the argument that Section 271(f) encompasses method patents. In any event, the impact of the Banner statement is limited at best. That statement, while apparently reflecting an interested party's views of the effect of a pending bill, is not persuasive regarding the meaning of the

enacted language. A statement by one private proponent of a pending bill in Congress, even if his testimony was that the bill was intended to encompass methods as well as apparatus patents, a matter not entirely clear from its language, cannot override the clear language of the statute and the context in which it was enacted. See McCaughn v. Hershey Chocolate Co., 283 U.S. 488, 493-94 (1931) (stating that "individual expressions are without weight in the interpretation of a statute"). Certainly in light of the statutory language and the overwhelming evidence of Congress's focus on patented products, that lone statement cannot carry the day for Cardiac.

Any ambiguity as to Congress's intent in enacting Section 271(f) is further resolved by the presumption against extraterritoriality. The Supreme Court took a narrow view of Section 271(f) by stating that the presumption against extraterritoriality still applies to Section 271(f), even though that section specifically extends the reach of U.S. patent law in a limited manner. AT&T II, 550 U.S. at 454-56. In light of the near complete absence of any Congressional intent to protect patented methods under Section 271(f) and the explicit Congressional purpose of overruling Deepsouth's holding, the presumption compels us not to exclude the reach of Section 271(f) to method patents.

In sum, the language of Section 271(f), its legislative history, and the provision's place in the overall statutory scheme all support the conclusion that Section 271(f) does not apply to method patents. We therefore overrule, to the extent that it conflicts

with our holding today, our decision in Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), as well as any implication in *Eolas* or other decisions that Section 271(f) applies to method patents.

We now turn to the facts of this case. Cardiac alleges that St. Jude violates Section 271(f) when it ships its ICDs outside of the United States. We disagree. Claim 4 of the '288 patent is comprised of the steps of determining a heart condition, selecting cardioversion as the appropriate therapy, and executing a cardioverting shock. Cardiac does not allege that all of those steps are carried out in the United States with respect to certain of the ICDs. Moreover, it cannot allege that the steps of the method are supplied, a contradiction in terms. Rather, Cardiac alleges that St. Jude's shipment of a device that is capable of performing the method is sufficient to fall within the scope of Section 271(f). Although the ICD that St. Jude produces can be used to perform the steps of the method, as we have demonstrated, Section 271(f) does not apply to method or process patents. As Section 271(f) does not encompass devices that may be used to practice a patented method, St. Jude is therefore not liable for infringement of claim 4 of the '288 patent under Section 271(f) for ICDs exported abroad.

D. Reassignment

Finally, Cardiac urges us to reassign this case to a different judge on remand. However, there is no evidence of, and Cardiac does not appear to allege, that Judge Hamilton has been partial or biased in

any way during the proceedings. We therefore decline to designate a judge to preside over the remand. We see no reason to interfere with the internal operations of the Seventh Circuit, and we leave the determination of assignment on remand to that circuit's internal rules and procedures.

CONCLUSION

For the foregoing reasons, we reverse the district court's grant of summary judgment of invalidity of the '288 patent and reinstate the jury verdict that the patent has not been shown to be invalid. We also reinstate the jury's verdict that the '288 patent is not unenforceable for inequitable conduct and reverse the district court's grant of a conditional new trial on that issue. We remand to the district court for a determination of damages. We affirm the district court's rulings limiting damages to instances in which the patented method has been performed. Finally, we reverse the court's decision that 35 U.S.C. § 271(f) is applicable to this case and hold that St. Jude's ICDs that practice the method of claim 4 outside the United States do not infringe that claim under Section 271(f).

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC., and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and ANNA MIROWSKI,

Plaintiffs-Appellants,

v.

ST. JUDE MEDICAL, INC., and PACESETTER, INC.,

Defendants-Cross Appellants.

Appeal from the United States District Court for the Southern District of Indiana in 96-CV-1718, Judge David F. Hamilton.

NEWMAN, Circuit Judge, concurring in parts A, B, C.1, and D, dissenting from part C.2.

I concur in the court's opinion except for the en banc ruling in part C.2. I respectfully dissent from the court's interpretation of 35 U.S.C. §271(f) as excluding all process inventions. The statutory term "patented invention" in §271(f) has the same meaning in this subsection as in every other part of Title 35: it

is the general term embracing all of the statutory classes of patentable invention. The court's interpretation of §271(f) to exclude all process inventions is contrary to the text of the statute, ignores the legislative history, is without support in precedent, and defeats the statutory purpose.

35 U.S.C. §271(f) was enacted to provide remedy to patentees for certain activity conducted outside of the United States, when that activity would be infringing if conducted within the nation's borders. Section 271(f) specifically concerns offshore activity where practice of a patented invention is "actively induced" by the supply of defined components from the United States, in which situation the supplier is deemed an infringer under §271(f). The statute is aimed at evasion of United States patents, and is not limited to any particular class of patentable subject matter. The court now holds, sitting en banc for the purpose, that the statutory term "patented invention" excludes process inventions in §271(f). That ruling, placing a different definition on "patented invention" in §271(f) than in any other provision of Title 35, is incorrect.

The statute is unambiguous

Section 271(f) contains two subsections. The court today holds that both parts exclude all process inventions from the "patented invention" of the statutory text, without discrimination or exception; the court imposes this reading despite the plain text of the statute, as follows (with emphases added):

§271(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a **patented invention**, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

§271(f)(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a **patented invention** that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Title 35 defines "inventions patentable" as including all patent-eligible subject matter, including processes:

> §101. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirement of this title.

Many sections of Title 35 use "invention" or "patented invention" or "patentable invention" when referring to all of the statutory classes of invention set forth in §101. E.g., §§102, 103, 104, 105, 181, 201, 286, etc.[1] When a specific statutory class is intended it is explicitly stated, as for example in §271(c) and (g), as explained post. The text of §271(f) states no such limitation, and presents no ambiguity in its use of "patented invention." The extreme redefinition here proffered for this subsection, unique within the entire statute, cannot be inferred from the use of "patented invention," without qualification, in §271(f).

The Supreme Court has stressed that "in interpreting a statute a court should always turn first to one, cardinal canon before all others. We have stated time and again that courts must presume that a legislature says in a statute what it means and

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[1] E.g., §102 (use of the term "invention" to refer to statutory subject matter); §103(a) (use of "invention" as synonymous with "subject matter sought to be patented"); §104 (describing rights in an "invention made abroad"); §105 ("invention made, used or sold in outer space"); §181(d) (defining "invention" as "any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act"); §286 (time limit on damages for infringement of a "patented invention").

means in a statute what it says there." Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-254 (1992). "When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" Id. at 254 (quoting Rubin v. United States, 449 U.S. 424, 430 (1981)). The Federal Circuit, too, has recognized that "[i]f the statute is unambiguous, our inquiry is at an end; we must enforce the congressional intent embodied in that plain wording." Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178, 1192 (Fed. Cir. 2004). The meaning of "patented invention" is unambiguously stated in 35 U.S.C. §101, for the entire statute.

The Supreme Court has previously so held. In Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) the Court addressed the term "patented invention" as it appears in §271(e), an infringement provision enacted six weeks before §271(f). The Court rejected the argument that the term "patented invention" in §271(e) was limited by other language in the provision to mean only drug patents, holding that "[t]he phrase 'patented invention' in §271(e)(1) is defined to include all inventions, not drug-related inventions alone." Id. at 665. The Court stated that if the statute had been intended to apply only to drug-related inventions, "there were available such infinitely more clear and simple ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected." Id. at 667.

My colleagues reach the opposite conclusion today, without mentioning the use of the identical

words "patented invention" by the same Congress that enacted §271(e) and soon thereafter enacted §271(f). It is not reasonable now to rule that the same words used in two adjacent subsections of the same statute, enacted by the same Congress in close temporal proximity, were intended to diverge radically from the statutory definition of "patented invention" and from each other.

The context of §271(f)

The statutory meaning of "patented invention" is reinforced upon observation of those sections of the Patent Act that are directed to particular categories of invention, as illustrated in §271 itself. The relationships and balance of the several provisions in subsections of this section demonstrate the statutory use of "patented invention" as the umbrella term for the forms of invention subject to the Patent Act, with narrower terminology used in those provisions that have narrower application. The §271 subsections deal with the various legislative remedies for various forms of infringement, as Congress acted to plug the loopholes that had arisen or were foreseen.

Reviewing the context of §271, we start with §271(a), the general infringement statute, directed to "any patented invention." Section 271(b) is directed to inducement of infringement of "a patent." All agree that subsections (a) and (b) apply to all statutory subject matter. Section 271(c) recites contributory infringement by a "component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process"; Congress thus

specified how contributory infringement occurs for the statutory categories. Section 271(d) relates to misuse of "a patent," citing specific commercial practices. Section 271(e) concerns "a patented invention" and although the statute refers to the drug regulatory context, the court in Eli Lilly, supra, explained that this term incorporates the entire subject matter of §101. Section 271(f) concerns the supply of components of "a patented invention" for use outside of the United States, again incorporating the subject matter of §101. Section 271(g), in contrast, is specific to the importation or sale of "a product which is made by a process patented in the United States." Each subsection is directed to different circumstances of infringement, and each recites its subject matter with generality or specificity, as appropriate.

Some amici curiae in this appeal suggested that since §271(g) specifically mentions practice of a patented process, then "patented invention" in §271(f) must exclude processes. That thesis is devoid of support. Subsections (g) and (f) are directed to distinct situations, for §271(g) requires importation or sale of the product of a patented process practiced abroad, before infringement can be established under that provision, while §271(f) does not require importation or sale, but instead requires that a component of the "patented invention" practiced abroad comes from the United States. Subsections 271(f) and (g) address quite different acts, and their subject matter is defined in accordance with the action that the specific statute is designed to remedy.

Section 271(c) is relied upon by the court as

somehow requiring that §271(f) excludes processes. Section 271(c) defines as "contributory infringement" acts that include the sale or importation into the United States of a non-staple article of commerce that is a "component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process," where the non-staple article constitutes a "material part of the invention" and is known to be made or adapted for the purpose of infringing, within the United States, a patented product or process. The text of §271(c) illuminates the text of §271(f), for §271(c) mentions the statutory classes in terms of how "contributory infringement" works, whereas §271(f)(1) is directed to inducement, and in the usage "patented invention" in both subparts, §271(f) states its independent scope. This is not an inadvertent distinction, in view of these heavily scrutinized provisions and their years of legislative consideration. My colleagues appear to have misinterpreted these distinct usages, for the different subsections reinforce that the legislators carefully structured each for a distinct purpose. See Russello v. United States, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion.").

The various subsections of §271 reflect the considered legislative approach to plug loopholes in the infringement statute, in the interest of United States patentees and in support of United States innovation. The close relationship among these and

all sections of the Patent Act "presents a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." Sullivan v. Stroop, 496 U.S. 478, 484 (1990) (quoting Sorenson v. Sec'y of Treasury, 475 U.S. 851, 860 (1986)). Nonetheless, the court today discards this rule, and holds that despite its consistent usage throughout the Patent Act, "patented invention" in §271(f) was intended to have a unique meaning, applicable only to this subsection, to exclude all processes from "patented invention."

The new loophole here created under §271(f) will outshine the simple evasion that led Congress and the innovation community to the carefully written texts of sections 271(c), (e), (f), and (g). These texts show that when legislation specific to one or another class of invention was intended, it was explicitly stated in those subsections of §271. "'It is not uncommon to refer to other, related legislative enactments when interpreting specialized statutory terms,' since Congress is presumed to have 'legislated with reference to' those terms." Reno v. Koray, 515 U.S. 50, 57 (1995) (quoting Gozlon-Peretz v. United States, 498 U.S. 395, 407-408 (1991)).

Legislative history and congressional intent

This congressional intent is confirmed by the legislative history. Various proposals were considered over many years before selecting the text that was enacted as §271(f). Beginning with the statutory loophole exposed in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), legislative

activity proceeded for a decade as new pitfalls were foreseen, new bills introduced, new hearings held, and new provisions written. For example, the early proposals suggested adapting the language in existing statutory provisions. See, e.g., Hearings Before the Subcomm. on Patents, Trademarks, and Copyrights of the Sen. Comm. on the Judiciary, 93rd Cong. 2871-74 (1973) (statement of Guy W. Shoup) (proposing amendment to overturn Deepsouth and stating that an "attempt has been made to track present statutory language as closely as possible, specifically 35 U.S.C. §271(b) and §271(c)"). The early bills borrowed directly from §271(c), as for instance in S. 2504, initially introduced on October 1, 1973. A committee print of that bill, as amended, shows the following text, with the relevant language emphasized:

> (f) Whoever, without authority, makes or sells, within the United States, all of the components of a patented machine, manufacture, or composition of matter, uncombined, intending that such components will be combined outside the United States to constitute the patented subject matter, knowing that if such components were combined within the United States, the combination would be an infringement of the patent, shall be liable as an infringer.

S. 2504, 93d Cong., 2d Sess. (comm. print dated May 8, 1974); see also S. 473, 94th Cong., 1st Sess., §271(e) (1975) (same text); S. 23, 94th Cong., 1st Sess., §271(f) (1975) (same text); S. 2255, 94th Cong., 1st

Sess., §271(f) (1975) (same text). Reprinted in Hearings Before the Subcomm. of Courts, Civil Liberties, and the Administration of Justice of the H.R. Comm. on the Judiciary, 98th Cong. 2859-69 (1984) ("Hearing Review"). It is seen that these early bills did not include processes, but were specific to "a patented machine, manufacture, or composition of matter."

Subsequent bills, including S.1535, 98th Cong., 1st Sess. (1983), replaced this specific text with the encompassing term "patented invention." The published record in the Hearing Review shows the understanding that the effect of this change is to cover processes as well as the other statutory categories. Contrary to the majority's suggestion, the legislative history is not limited to an ambiguous private statement by an "interested party," see maj. op. at 28, for the Hearing Review demonstrates that the executive branch considered it important that the statute cover process inventions. The Hearing Review contains a report prepared by the Patent and Trademark Office for the Justice Department, observing that the Deepsouth holding had been applied to process patents in John Mohr & Sons v. Vacudyne Corp., 354 F. Supp. 1113 (N.D. Ill. 1973), and stating that "[n]o reasons exist for treating process patents differently from product patents in this regard, and therefore, the Mohr case should also be overturned." Hearing Review at 2897. The majority has not controverted the clear evidence that the change in statutory language was for the purpose of encompassing processes.

The ensuing change in legislative language,

embodied in S.1535, demonstrates the purposeful action to include processes in §271(f), instead of the more limited scope of earlier versions of the legislation. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." Russello, 464 U.S. at 23-24 (citing Arizona v. California, 373 U.S. 546, 580-81 (1963)). This broadening of statutory protection, over the decade of hearings and review that followed the Deepsouth decision, reflects a careful and deliberative process, as additional concerns were exposed and additional subsections proffered, in a collaborative legislative effort to reinforce the value of the patent statute as an innovation incentive. As the Court observed in Oncale v. Sundowner Offshore Serv., Inc., 523 U.S. 75, 79 (1998), "statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." Here, in plugging the Deepsouth loophole, Congress eventually enacted a statute directed to all classes of patentable invention. Yet this court curiously returns to the precise words that were initially proposed and then explicitly superceded.

Plain language and contemporary context

It is a canon of statutory construction that the statute must be understood in its contemporary context. The Court stated in Cannon v. University of Chicago, 441 U.S. 677, 696-97 (1979), that "it is always appropriate to assume that our elected representatives, like other citizens, know the law . . .

and that an evaluation of congressional action taken at a particular time must take into account its contemporary legal context." Despite the clarity of "patented invention" in §271(f), and the context of concern for statutory loopholes inimical to the interest of innovators in the United States, this court now rules that the legislators intended to preserve a large loophole for patented processes, and never intended to cover more than the narrow Deepsouth loophole for machinery.

Despite the multiple manifestations of legislative intent, in the plain language, the statutory context, and the evolution of §271(f), my colleagues now rule that in one and only one subsection of Title 35, "patented invention" excludes process inventions. My colleagues state that they agree that the plain meaning of "patented invention" is fixed by §101, yet they decide that Congress cannot have meant what it said, and that this plain meaning is defeated by hidden meaning in §271(f). The Court has cautioned that such a statutory interpretation can arise only in "rare and exceptional circumstances," Crooks v. Harrelson, 282 U.S. 55, 58 (1930) (rejecting argument to ignore literal meaning of a statute based on Holy Trinity Church v. United States, 143 U.S. 457 (1892), and stating that a court may "override the literal terms of a statute only under rare and exceptional circumstances"). Such circumstances are not present here.

My colleagues seek support in the statutory words "components" and "supply." The en banc court concedes that processes have "components," but argues that process components cannot be "supplied"

from the United States to a foreign operation, because the steps of a process are intangible. However, process information, as well as the results of process steps, are readily supplied from one entity to another. The Court recently noted, in a case under §271(f) involving products, that "[i]f an intangible method or process . . . qualifies as a 'patented invention' under §271(f) (a question as to which we express no opinion) the combinable components of that invention might be intangible as well." Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 452 n.13 (2007). My colleagues' opinion mentions tangibles and intangibles, but does not apply §271(f) to the claimed process.

Although the facts of infringement are not developed on the en banc record, enough is before this court to show that the claim is not for an abstract, disembodied process. In addition, the claims include both method and structural aspects. See '288 patent, Claim 1 (reciting method "using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia"); Claim 4 (reciting "mode of operation of said implantable heart stimulator").

It appears that the heart stimulator is supplied from the United States and combined with process steps that are taught from the United States and performed abroad. Although both product and process aspects are involved, the court presents no findings concerning the nature of the components supplied from the United States. It may also be relevant that in Quanta Computer, Inc. v. LG

Electronics, Inc., 128 S. Ct. 2109, 2117-18 (2008), the Court reminded us that: "Apparatus and method claims 'may approach each other so nearly that it will be difficult to distinguish the process from the function of the apparatus.'" (quoting United States ex rel. Steinmetz v. Allen, 192 U.S. 543, 559 (1904)). Such complex issues have not been brought out on this appeal, because they were not presented in the winner-take-all question presented for en banc briefing.[2] The court's new statutory interpretation is far more sweeping than is needed to decide this case, and far simpler than today's technology deserves. The challenge of applying important and complex law to new facts is poorly met by holding that no law applies to any facts.

It is well recognized that a process has parts, or "components"; this is a general term applicable to all inventions. In Microsoft, 550 U.S. at 449 n.11, the Court, in discussing §271(f), noted that "component" is defined as "a constituent part," "element," or "ingredient," quoting Webster's Third New International Dictionary of the English Language; and as the majority acknowledges, the Court stated that for a process invention, the "combinable components of that invention might be intangible," id. at 452 n.13. In a discussion of process claims in

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[2] The court invited briefing limited to the question "Does 35 U.S.C. §271(f) apply to method claims, as well as product claims? Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., No. 07-1296 (order granting rehearing en banc) (Fed. Cir. March 6, 2009).

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997), where the patent was for a purification process, the Court stated the inquiry as: "Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" Id. at 40. Throughout our own precedent this court has, without quibble, described a step in a process or method as an element of the process or method. See, e.g., Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1328 (Fed. Cir. 2009) ("In summary, during the 1989 demonstration, all elements of the repair method in claim 1 of the '307 Patent were performed."); Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1214 (Fed. Cir. 2008) ("This court has consistently interpreted 'including' and 'comprising' to have the same meaning, namely, that the listed elements (i.e., method steps) are essential but other elements may be added.").

Each step of a process is a component thereof, which, when combined with the other steps, performs the process. In BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (2007), this court held that process claims are infringed when some steps are practiced by one entity and other steps are practiced by another, provided that the charged entity controls or directs the conduct of the other, the court explaining that: "A party cannot avoid infringement, however, simply by contracting out steps of a patented process to another entity." Id. at 1381. The court concluded that the practice of steps of the patented method can be combined, whereby the party that performs earlier steps "supplies" this component to the party that performs the later steps. This

principle is commensurate with the application of §271(f) to processes that are partly performed in the United States. Surely there is no cause to conclude, as the majority concludes, that it is a "physical impossibility" to read §271(f) as applying to processes. Maj. op. at 26.

On the established understanding of how processes are performed, it cannot be ruled that the words "component" and "supply" in §271(f)(1) impart a unique meaning that defeats the plain text of the statute. It cannot be ruled that Congress, along with all of the contributors to this legislation, who understood and intended the use of general terms to embrace all forms of patented invention in Title 35, nonetheless silently eliminated patented processes from "patented invention" in §271(f).

Sovereignty Issues

I share every court's concern about legislatively impinging upon sovereign foreign rights. In this case, however, the statutory purpose is to reach the evasion of United States rights by actions that are taken within the United States by entities subject to United States law. The practice in foreign countries of United States–origin technology without any contribution of components from the United States is untouched by §271(f), whether of process or product. Liability under §271(f) is based on domestic conduct and intent.

Although protection in foreign countries can sometimes be had by obtaining and enforcing foreign patents, as mentioned in Microsoft, 550 U.S. at 456,

that expensive alternative may not be available. When a patented process is practiced so that some steps are performed in the United States and other steps are performed offshore, the purloiner of the patented process may escape liability everywhere, for United States infringement is avoided if all of the process steps are not practiced in the United States, and infringement of foreign patents is avoided for the same reason. It cannot be that the legislators intended to enable avoidance of process patents by this ploy, while correcting it for machine patents. A statutory interpretation that results in all process inventions being seriously devalued, is not free of the charge of "absurd result." See Dewsnup v. Timm, 502 U.S. 410, 427 (1992) (the interpretation of a statute should "avoid absurd results").

St. Jude and several amici curiae observe that some countries do not permit patenting of medical procedures, and cite this as a reason for refusing all remedy under §271(f) for any practice abroad of any infringing process in any aspect of technology. This reasoning is insupportable in the broad thesis proposed by the amici. And as to the specific patent in suit, as Cardiac points out, a medical device such as a defibrillator and its method of use are generally viewed as patentable in most countries.

Concerns of amici curiae

Several amicus curiae briefs expressed concern that a broad construction of §271(f) could lead to unfair liability for United States providers of computer-based systems. Thus these amici proposed that blanket removal of all process inventions—the

yes-or-no question here posed by this court—would best meet the needs of their industries. True, this court's inquiry was insufficiently nuanced, for such a blunderbuss attack on all process technologies is not needed to serve the asserted special needs of information industries. However, my colleagues have over-reacted as well as over-reached, for it is not necessary (nor is it our prerogative) to destroy the statute for all process industries, in order to avert potential abuses in unknown circumstances. I agree that for ever more complex technologic facts, vigilance is required to preserve the statutory purpose. As in all areas of evolving interests and policy, if statutory change is warranted, it should be achieved with the participation of all those affected. It is not the judicial role to dump the statute entirely, as overreaction to the facts of one case. The court's decision today is as unnecessary as it is incorrect.

The simple purpose of §271(f) is that, for patented inventions, a United States patent cannot be avoided by providing substantial components from the United States while performing some aspect offshore to avoid a technical act of infringement under §271(a). Section 271(f) draws no distinction between process and product inventions, and such distinction is unrelated to the legislative purpose. As Judge Learned Hand reminds us, "statutes always have some purpose or object to accomplish:"

> "[I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else.

> But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning."

Cabell v. Markham, 148 F.2d 737, 739 (2d Cir.), aff'd, 326 U.S. 404 (1945).

The court's ruling reopens, for process inventions, the loophole that was plugged by §271(f) for all patented inventions. The extensive legislative record shows consideration of equity, economics, innovation incentive, and international concerns, in the evolution of the text of §271(f). The en banc court makes no mention of any of these concerns, and does not discuss the consequences of today's holding in negating the legislative purpose. I respectfully dissent from the court's statutory interpretation and the decision based thereon.

Appendix B

United States Court of Appeals
for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC.
and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and
ANNA MIROWSKI,

Plaintiffs-Appellants,

v.

ST. JUDE MEDICAL, INC.,
and PACESETTER, INC.,

Defendants-Cross
Appellants.

Appeals from the United States District Court for the Southern District of Indiana in 96-CV-1718, Judge David F. Hamilton.

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges.

PER CURIAM

ORDER

Combined petitions for panel rehearing and rehearing en banc were filed by both the Plaintiffs-Appellants and the Defendants-Cross Appellants. The court invited a response to the petition of Defendants-Cross Appellants and asked that the response be limited to the issue concerning construction of 35 U.S.C. § 271(f). Plaintiffs-Appellants filed a response. The court granted the Federal Circuit Bar Association, et al., and Cisco Systems, et al., motions for leave to file briefs as amici curiae.

The petition for rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and the court has decided that the appeal warrants en banc consideration.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) Both petitions for panel rehearing are denied.

(2) The petition of Defendants-Cross Appellants for rehearing en banc is granted.

(3) The court's December 18, 2008, opinion is vacated and the appeal is reinstated.

(4) The petition of Plaintiffs-Appellants for rehearing en banc is denied.

(5) The parties are requested to file new briefs addressing only the following question:

1) Does 35 U.S.C. § 271(f) apply to method claims, as well as product claims?

This appeal will be heard en banc on the basis of briefs addressing the issue set forth above. An original and thirty copies of all briefs shall be filed, and two copies served on opposing counsel. The Defendants-Cross Appellants shall file a brief within thirty (30) days from the date of filing of this order. The Plaintiffs-Appellants' response brief is due within twenty (20) days from the date of service of the Defendant-Cross Appellants' brief. The Defendants-Cross Appellants' reply brief, if any, is due seven (7) days from the date of service of the Plaintiffs-Appellants' brief. Briefs shall adhere to the type-volume limitations set forth in Federal Rule of Appellate Procedure 32 and Federal Circuit Rule 32.

Briefs of amici curiae will be entertained, and any such amicus briefs may be filed without leave of court but otherwise must comply with Federal Rule of Appellate Procedure 29 and Federal Circuit Rule 29.

The parties and amici should not anticipate any extensions of time for the briefing schedule. Oral argument will be held at 2 P.M. on Monday, June 1, 2009, in Courtroom 201.

FOR THE COURT

March 6, 2009

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Arthur I. Neustadt, Esq.
J. Michael Jakes, Esq.
Denis R. Salmon, Esq.
Mark M. Supko, Esq.
Edward R. Reines, Esq.

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U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

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Appendix C

United States Court of Appeals
for the Federal Circuit

2007-1296, -1347

CARDIAC PACEMAKERS, INC.
and GUIDANT SALES CORPORATION,

Plaintiffs-Appellants,

and

MIROWSKI FAMILY VENTURES, LLC and
ANNA MIROWSKI,

Plaintiffs-Appellants,

v.

ST. JUDE MEDICAL, INC.,
and PACESETTER, INC.,

Defendants-Cross
Appellants.

Appeals from the United States District Court for the Southern District of Indiana in 96-CV-1718, Judge David F. Hamilton.

DECIDED: December 18, 2008

Before NEWMAN, MAYER, and LOURIE, Circuit Judges.

LOURIE, Circuit Judge

Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively "Cardiac" or "appellants") appeal from the decision of the United States District Court for the Southern District of Indiana granting summary judgment of invalidity of claim 4 of U.S. Patent 4,407,288 ("the '288 patent"). See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 483 F. Supp. 2d 734 (S.D. Ind. 2007) ("Invalidity Decision"). St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St. Jude") cross-appeal the district court's decision permitting damages under 35 U.S.C. § 271(f). See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 418 F. Supp. 2d 1021, 1027-30 (S.D. Ind. 2006) ("Damages Decision"). Because the district court erred in concluding that it could find the '288 patent anticipated, we reverse on invalidity. As infringement has already been decided by the court, we remand the case for a determination of the damages award. Such a determination should be made in accordance with the district court's prior rulings, which we affirm, limiting damages to those devices that can be shown to have executed the steps comprising claim 4 of the '288 patent.

BACKGROUND

This is a patent dispute relating to implantable cardioverter defibrillators that has been before us on four previous occasions. See Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 296 F.3d 1106 (Fed. Cir. 2002); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed. Cir. 2004) ("2004 Opinion");

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 144 Fed. Appx. 106 (Fed. Cir. 2005) ("2005 Reassignment Order"); In re Cardiac Pacemakers, Inc., 183 Fed. Appx. 967 (Fed. Cir. 2006) ("2006 Writ Order"). Three of our prior decisions, the 2004 Opinion, the 2005 Reassignment Order, and the 2006 Writ Order, are at issue in this appeal.

Implantable cardioverter defibrillators ("ICDs") are small devices that detect and correct abnormal heart rhythms that can be fatal if left untreated. Defibrillators work by administering electrical shocks to the heart, those shocks being calibrated to restore normal heart functioning. There are different types of electrical shocks that defibrillators can be programmed to administer, including pacing shocks (which are relatively low power shocks), defibrillation (relatively high power shocks), and cardioversion, the definition of which has been a source of dispute throughout the protracted litigation of this case.

Cardiac owns various patents relating to cardiac defibrillators, including the '288 patent. The '288 patent claims a method of heart stimulation using an implantable heart stimulator that is capable of detecting heart arrhythmias, or irregular heart rhythms, and of being programmed to treat the arrhythmia through either single or "multimode" operation. Multimode operation allows defibrillators to respond to arrhythmias by applying first one type of shock and then, if unsuccessful, administering a second type of shock. Multimode allows an implantable cardioverter defibrillator to administer various types of shocks consecutively until the normal heart rhythm is restored.

Cardiac brought an infringement action against St. Jude, accusing St. Jude of selling ICDs that infringed Cardiac's patents. In 2001 the case went to trial, and a jury returned a verdict awarding Cardiac $ 140 million in royalties for infringement of U.S. Patent 4,316,472 ("the '472 patent"). As for the '288 patent, the jury found the patent valid and enforceable, but not infringed by St. Jude's ICDs. The jury rejected St. Jude's arguments that the invention of the '288 patent was obvious in light of various prior art references, including U.S. Patent 3,805,795 ("Denniston") and United Kingdom Patent Application 2,026,870 ("Duggan"). The jury also rejected St. Jude's argument that the '288 patent was unenforceable for inequitable conduct.[1]

Following the trial, the district court granted several post-verdict motions that overturned the jury verdict and conditionally granted a new trial on several issues that St. Jude had lost at trial. The court granted St Jude's JMOL motions holding the '472 patent not infringed and invalid, as well as St. Jude's motion for a conditional new trial on damages. That decision vacated the damages awarded by the jury. Cardiac has not appealed any of the court's decisions regarding the '472 patent.

Regarding the '288 patent, the district court denied Cardiac's request for a new trial on infringement. Cardiac had claimed that it had been

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[1] The jury also rejected St. Jude's argument that the '288 patent failed to comply with the best mode requirement of 35 U.S.C. § 112 ¶ 1. St. Jude has not appealed any decisions relating to 35 U.S.C. § 112 in this appeal.

denied a fair trial on the '288 patent due to St. Jude's opening statement and presentation about the inconsistent reports of Dr. Joseph Bourland, one of Cardiac's primary experts. The court also granted St. Jude's JMOL motion and request for a new trial, finding that the '288 patent was invalid on the grounds of obviousness and lack of best mode. The court denied St. Jude's JMOL motion of unenforceability in which St. Jude argued that the '288 patent was unenforceable due to Cardiac's alleged failure to pay proper maintenance fees.

Following the district court's decisions, Cardiac appealed the court's grant of JMOL of invalidity of the '288 patent as well as the court's rejection of JMOL of infringement of claim 4 of that patent. On appeal, we reversed on both issues. Regarding validity, we held that there was "substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion," and therefore reinstated the jury verdict that the "'288 patent is not invalid for obviousness." 2004 Opinion 381 F.3d at 1378-80. We also found that the district court's conditional grant of a new trial on obviousness "exceeded the court's discretionary authority." Id. at 1380.

Regarding infringement, we reversed the court's claim construction and therefore vacated the jury's finding of non-infringement. We held that the district court had erred in finding that the "determining" step of claim 4 was a "step-plus-function" limitation under 35 U.S.C. § 112 ¶ 6 and remanded the case to the district court to modify the claim construction of the

"determining" step in accordance with our opinion. Id. at 1382. Lastly, we agreed with St. Jude that our reversal of the district court's claim construction entitled St. Jude to a "jury determination on the question of infringement." Id. at 1383.

We summarized our holding as follows:

> We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial on infringement and reassessment of damages.

Id. at 1374.

On remand, the case was returned to Judge Hamilton. Cardiac challenged the assignment, claiming that Seventh Circuit Rule 36 required automatic reassignment of a case remanded for a new trial to a new judge. Judge Hamilton ultimately agreed with Cardiac and agreed to reassign the case. He then certified the issue for an interlocutory appeal. St. Jude appealed the reassignment decision to this court, and we reversed, finding that reassignment to Judge Hamilton would best conserve judicial resources. 2005 Reassignment Order, 144 Fed. Appx. at 106. We also noted that the case had been remanded for "a new trial on literal infringement of one claim of one patent and for any damages determination." Id. at 107.

After this remand, both sides submitted to the district court proposed claim constructions for the disputed "determining" limitation in claim 4 of the '288 patent, and the district court adopted Cardiac's

definition of "determining" with one minor change (which is not challenged on appeal). Damages Decision, 418 F. Supp. 2d at 1027-30. Cardiac also moved for summary judgment on St. Jude's invalidity and unenforceability defenses, arguing that such defenses were precluded by our 2004 Opinion and the mandate rule. The district court disagreed and denied the motion. The court found that "[t]he Federal Circuit's remand left open the possibility of new invalidity and unenforceability defenses." Id. at 1031. According to the district court, while the mandate rule precluded assertion of the same obviousness argument raised and lost previously, "St. Jude's other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand." Id. at 1032. In arriving at that conclusion, the district court relied on three points. First, the court found that our remand instructions "suggested" that a new claim construction might give rise to new invalidity defenses, particularly with regard to the adequacy of the written description requirement. Id. Second, the court found that because St. Jude had no obligation on appeal to present alternative arguments for invalidity, those alternative arguments were not precluded on remand. Id. at 1032-33. Third, and most importantly, the court found that St. Jude did not abandon or waive its invalidity defenses that became relevant only on remand; that is, due to the court's new claim construction of "determining," certain prior art that was not invalidating under the erroneous claim construction may have become invalidating under the new claim construction. Id. at 1033.

The district court also rejected Cardiac's motion for summary judgment on St. Jude's affirmative

defenses and related counterclaims. The court found that "all of St. Jude's arguments concerning unenforceability" could be asserted on remand. Id. The district court found that this court's mandate "did not even suggest, let alone require," that the issue of inequitable conduct be precluded from adjudication on remand. Id. at 1034.

Finally, the district court granted in part and denied in part St. Jude's motion for summary judgment limiting damages. The court granted St. Jude's motion to limit damages to ICDs that actually performed the claimed steps. Id. at 1040. The court held that because claim 4 is a method claim, only those devices that "can be shown to have executed" the claimed method were to be used in the damages calculation. Id. at 1042. However, the court rejected St. Jude's motion to limit damages to U.S. sales of ICDs. The court held that, according to Federal Circuit case law on 35 U.S.C. § 271(f), Cardiac was not limited in its potential damages award to infringing devices that were sold in the United States. Id. at 1042-44.

Following the district court's ruling on claim construction and summary judgment, Cardiac petitioned this court for a writ of mandamus directing the district court to vacate its order allowing St. Jude to assert invalidity and inequitable conduct defenses on remand. We denied the petition. In doing so, we stated:

> [W]e repeat that we "remand[ed] for a new trial of infringement and reassessment of damages," including re-construction by the district court of the "determining" provision in light of our ruling that *section* 112 ¶ 6 did not apply. We also recognized that a new claim construction may raise directly related new issues, "such as whether the now-asserted scope of the claims is supported by the specification."
>
> All of the other issues on remand were finally decided, and are not subject to reopening on remand.

2006 Writ Order, 183 Fed. Appx. at 967 (citations omitted) (emphasis added). The case was once more remanded to the district court.

On March 26, 2007, the district court granted Cardiac's motion for summary judgment of infringement, while also granting St. Jude's motion for summary judgment of anticipation. As a threshold matter, the district court found that because of the new, broader claim construction, the anticipation defense was, in the words of this court, a "directly related new issue," and therefore not precluded by our previous decisions. Invalidity Decision, 483 F. Supp. 2d at 738-739. The court then turned to the prior art and found that the '288 patent was anticipated by two references that had been previously presented to the jury: Denniston and Duggan. Final judgment was entered by the district court.

Cardiac timely appealed and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment de novo, "applying the same criteria used by the district court in the first instance." Rothe Dev. Corp. v. Dep't of Defense, 545 F.3d 1023, 1035 (Fed. Cir. 2008) (quoting W.H. Scott Constr. Co. v. City of Jackson, 199 F.3d 206, 211 (5th Cir. 1999)). Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). We review the interpretation of our own mandates de novo. Engel Indus., Inc. v. Lockformer Co., 166 F.3d 1379, 1382 (Fed. Cir. 1999).

A. Invalidity

On appeal, Cardiac argues that the district court erred in granting summary judgment of invalidity. Preliminarily, Cardiac argues that invalidity was not at issue on remand because the mandate rule precluded St. Jude's anticipation defense. If we find that anticipation was still at issue on remand, Cardiac argues that we should also find that the district court erred in finding that genuine issues of material fact did not exist as to whether Duggan and Denniston were anticipating references, particularly with respect to whether Duggan teaches cardioversion and whether Denniston teaches programming.

In response, St. Jude argues that while the mandate rule bars consideration of obviousness on remand, it does not bar an anticipation defense. According to St. Jude, our reversal of the "determining" construction in the 2004 Opinion created new validity defenses due to the changed claim scope. St. Jude also claims that the *'288 patent* was anticipated by both Denniston and Duggan, as the district court found.

We agree with Cardiac that anticipation was not properly before the district court on remand. In the 2004 Opinion, we clearly stated that the purpose of the remand was "for a new trial of infringement and reassessment of damages." 2004 Opinion, 381 F.3d at 1374. Furthermore, we explicitly "reinstate[d] the jury verdict of validity." Id. The mandate rule requires that the district court follow an appellate decree as the law of the case. See Sibbald v. United States, 37 U.S. 488, 492, 9 L. Ed. 1167 (1838). Therefore, according to our explicit instructions, any new trial on remand was limited to an assessment of infringement and a calculation of any damages.

Of course, as St. Jude rightly notes throughout its briefs, our 2004 Opinion altered the district court's claim construction, and in the 2006 Writ Order we left open the possibility that a new claim construction ruling "may raise directly related new issues." 2006 Writ Order, 183 Fed. Appx. at 967. As one example of a directly related new issue, we noted the question whether the scope of the claims under the new claim construction was supported by the specification. Id. We did not explicitly include or exclude anticipation

from the list of possible new issues raised by a new construction of "determining."

Thus, the question before us today is whether anticipation is a "directly related new issue," or whether our reinstatement of the jury's validity verdict precludes raising anticipation on remand. In this case, a jury found that the '288 patent was nonobvious in light of numerous prior art references, including both Duggan and Denniston. At trial, Cardiac did not dispute that the "determining" step was in the prior art and did not raise that step as a distinguishing feature between the '288 patent and Duggan or Denniston. See Reply Brief of Plaintiffs-Appellants at 12-14, 2004 Opinion (arguing that Duggan and Denniston do not teach cardioversion); Brief of Plaintiffs-Appellants at 21-24, 2004 Opinion, 381 F.3d 1371 (Fed. Cir. 2004) (arguing that the jury heard evidence that the prior art did not teach "cardioversion," "multi-mode operation," and "programmability"); but see id. at 22 (noting evidence that the Baker reference does not perform, among other things, the determining step). In fact, the evidence of obviousness during the trial primarily focused on whether the prior art taught multi-mode with cardioversion. See Brief for Defendants-Cross Appellants at 7-8, 2004 Opinion (stating that with regard to obviousness, the only disputed limitations were the claimed invention's ability to perform multimode operation and the use of cardioversion). In finding the claims of the '288 patent nonobvious, the jury reached the conclusion that some element necessary to prove obviousness had not been demonstrated. For St. Jude to succeed in this appeal, that missing element would have to have been the

"determining" limitation.

In allowing St. Jude's anticipation defense on remand, the district court stated that due to the erroneous claim construction, "St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial." Damages Decision, 418 F. Supp. 2d at 1033. While it is true that new anticipation arguments may arise under a change in claim construction, that cannot be the case here because the "determining" limitation never served as a basis for distinguishing the prior art from the '288 patent. Duggan and Denniston were not only known to St. Jude before trial, but both references were presented to the jury. The jury found that those references did not invalidate the patent even though Cardiac did not dispute that the "determining" construction was known in the prior art. Thus, it cannot be said that the jury's decision hinged on the erroneous construction of that claim. Stated differently, the jury's verdict of validity could not have depended upon the erroneous construction of "determining" because it was uncontested during trial that that term was present in the prior art.

The initial, erroneous construction of "determining" was appealed by Cardiac in order to challenge the jury's verdict of non-infringement. While a change in claim construction often may affect a jury's validity determination, in this case it does not. Therefore, St. Jude cannot now be allowed to claim that its anticipation arguments involving Duggan and Denniston are "directly related" to the change in the construction of "determining," because the jury's validity determination, which we

reinstated, did not depend upon that erroneous definition.

We therefore reverse the district court's summary judgment of invalidity and reinstate the jury's verdict that the '288 patent has not been shown to be invalid.

B. Inequitable Conduct

Cardiac asks this court to instruct the district court that enforceability defenses are precluded from any remand order. According to Cardiac, the mandate rule requires such a determination. St. Jude counters that inequitable conduct is still at issue on remand because of the district court's explicit ruling that "in the event of a new trial . . . the inequitable conduct defense shall be part of the trial." Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., No. IP-96-1718-C, 2002 U.S. Dist. LEXIS 14767, at *143 (S.D. Ind. July 5, 2002). Because Cardiac failed to appeal this ruling, St. Jude contends, that decision is final.

The district court characterized St. Jude's inequitable conduct arguments as falling into three broad categories. The first category involved misrepresentations made before the PTO. Damages Decision, 418 F. Supp. 2d at 1033-34. Some of these arguments were raised by St. Jude at trial and rejected by the jury. Id. at 1034. Others were raised and abandoned at trial. Id. The second category of arguments involved three patents that are no longer at issue in this case. St. Jude alleges that they were asserted even though Cardiac knew that they were invalid. Id. The district court granted Cardiac's

motion for summary judgment on these arguments, and St. Jude did not appeal that decision. Id.

We conclude that St. Jude has waived both categories of the arguments above. St. Jude either failed to pursue those arguments at trial, thereby waiving the arguments, or failed to appeal the arguments to this court. Id. St. Jude cannot now be heard to raise those arguments again on remand.

A third category of inequitable conduct arguments relates to misrepresentations made by Cardiac's expert, Dr. Bourland. The jury rejected many of St. Jude's inequitable conduct arguments based on Dr. Bourland's conduct, and the district court declined to reverse the jury's decision. However, due to revelations that came to light after trial, the court found that Dr. Bourland's conduct entitled St. Jude to a new trial. Cardiac, 2002 U.S. Dist. LEXIS 14767, at *143. In September 2006, the parties filed a stipulation stating that St. Jude would not pursue any defense based in whole or in part on Dr. Bourland's conduct. Following this stipulation, Cardiac filed a renewed motion for summary judgment on inequitable conduct. The district court never ruled on Cardiac's renewed motion because it entered a final judgment on anticipation on March 26, 2007.

With the stipulation removing Dr. Bourland's conduct as a basis for an inequitable conduct defense, St. Jude cannot now be heard to raise inequitable conduct on remand. Any language from the district court's opinion indicating otherwise would be an abuse of the court's discretion to grant a new trial.

We therefore reinstate the jury's verdict of enforceability of the '288 patent and hold that enforceability should not form part of any new trial on remand.

C. Damages

Cardiac argues that the district court erred by limiting damages to those ICDs that actually performed cardioversion during the infringement period. According to Cardiac, St. Jude waived its damages argument by not raising it at trial. Furthermore, Cardiac argues, Stryker Corp. v. Intermedics Orthopedics, Inc., 96 F.3d 1409 (Fed. Cir. 1996), and other cases have held that it is appropriate for patentees to recover damages based on sales of products with the mere capability to practice the invention.

St. Jude responds that it is not precluded from arguing for limited damages because the remanded damages assessment was significantly altered from the assessment that occurred at trial. Because Cardiac is now asserting only a method claim, St. Jude contends, any damages claim must be limited accordingly. Furthermore, in a cross-appeal, St. Jude argues that the district court erred in concluding that Cardiac could recover damages for overseas sales of St. Jude's ICDs under 35 U.S.C. § 271(f).

We agree with St. Jude that damages must be limited to those devices that were shown to infringe the '288 patent, but we reject St. Jude's cross-appeal seeking to limit overseas damages. As a preliminary matter, we find that St. Jude has not waived its

argument to limit damages. The jury was presented with a damages decision regarding two claims of the '288 patent: an apparatus claim that has since been abandoned by Cardiac and the method claim (claim 4) that is at issue on appeal. While both patent claims were at issue during trial, St. Jude would not have benefited if it had moved to limit damages because the damages on the apparatus claims would have covered any sale of an apparatus that could execute the elements of the claims. However, now only a method claim is at issue; thus, St. Jude stands to benefit from limiting damages to devices that actually practice the method. As the district court noted, the purpose of the waiver rule is to prevent a party from arguing on remand what it should have argued at trial or on appeal. Damages Decision, 418 F. Supp. 2d at 1035 (citing Tronzo v. Biomet, Inc., 236 F.3d 1342, 1347-48 (Fed. Cir. 2001)). St. Jude cannot have been expected to raise at trial an argument that would not have reduced damages until after Cardiac abandoned its apparatus claim on remand.

The district court was also correct in limiting damages to sales of ICDs that performed the steps of the claimed method. Cardiac disputes the district court's ruling by pointing this court to Stryker, in which we affirmed a district court's decision awarding damages on sales of an infringing prosthesis, even in cases in which a distal sleeve, a required element of the claim, was not included. See Stryker, 96 F.3d at 1416-17. The holding in Stryker is distinguishable from this case by the type of damages being sought and the type of patent being asserted. In Stryker, the patentee was seeking lost profits on an apparatus claim. We held, based on the

particular facts of that case, that the patentee was entitled to profits on the sale of all devices, with or without the required distal sleeve because the sale of the device robbed the patentee of "the opportunity to make the sale." Id. at 1417. This was true because the sleeve, while not included in every sale, was available to the surgeon during surgery. Id.

In the present case, however, Cardiac is not seeking lost profits on an apparatus and therefore cannot rely on the reasoning in Stryker. Here, Cardiac seeks royalties on its patented method. "A method claim is directly infringed only by one practicing the patented method." Joy Tech. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993). Thus, regarding claim 4 of the '288 patent, infringement can only occur in cases in which the patented method is practiced. In Stryker, the court found that because the entire patented apparatus was "supplied" during surgery, the patent was infringed by any sale of the device. Stryker, 96 F.3d at 1416-17. In this case it cannot be said that St. Jude has somehow "supplied" all of the elements of Cardiac's patented method through its devices unless those devices actually performed all of the steps required by the claims. "The law is unequivocal that the sale of equipment to perform a process is not a sale of the process." Joy Tech., 6 F.3d at 773. Therefore, Cardiac can only receive infringement damages on those devices that actually performed the patented method during the relevant infringement period. We thus affirm the district court's ruling.

We also affirm the district court's ruling on the application of 35 U.S.C. § 271(f) to this case. St. Jude

urges us to hold that the Supreme Court's decision in Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 127 S. Ct. 1746, 167 L. Ed. 2d 737 (2007) overturns this court's prior precedents that have held that § 271(f) applies to method claims. We do not agree. As St. Jude admits, the Supreme Court "left open the question of whether *Section* 271(f) applies to method claims." Appellees' Brief at 62. St. Jude would have us extend the reasoning behind the Supreme Court's decision in AT&T to overturn this court's decision in Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005) (holding that Section 271(f) applies to components used in the performance of patented methods and processes). We decline to do so. While this court was not unanimous in its approval of the holding in Union Carbide, see Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 434 F.3d 1357, 1358-59 (Fed. Cir. 2006) (Lourie, J., Michel, J., and Linn, J., dissenting from order denying rehearing en banc), the Supreme Court's decision does not alter that holding. As a panel, we cannot reverse the holding of another panel of this court. We thus affirm the district court's decisions relating to damages.

D. Reassignment

Finally, Cardiac urges this court to reassign the case to a different judge on remand. However, there is no evidence of, and Cardiac does not appear to allege, that Judge Hamilton has been impartial or biased in any way during the proceedings. We therefore refuse to designate the proper judge to preside over the remand. As an appellate court, we must review decisions stemming from the internal

procedures of district courts around the country. We should not, however, be in the habit of dictating to those district courts how they should conduct their internal affairs prior to any decision being made in a particular case. We see no reason to interfere with the internal operations of the Seventh Circuit, and leave the determination of assignment on remand to that circuit's internal rules and procedures.

CONCLUSION

For the foregoing reasons, we reverse the district court's grant of summary judgment of invalidity of the '288 patent and reinstate the jury verdict that the patent has not been shown to be invalid. We also reinstate the jury's verdict that the '288 patent is not unenforceable for inequitable conduct and reverse the district court's grant of a conditional new trial on that issue. We remand to the district court for a determination of damages. We affirm the district court's rulings limiting damages to instances in which the patented method has been performed and permitting the application of 35 U.S.C. § 271(f).

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

Appendix D

United States Court of Appeals for the Federal Circuit

02-1532, -1559

CARDIAC PACEMAKERS, INC., GUIDANT SALES CORPORATION and ELI LILLY AND COMPANY,

Plaintiffs-Appellants,

and

ANNA MIROWSKI,

Plaintiff-Appellant,

v.

ST. JUDE MEDICAL, INC., PACESETTER, INC., and VERITEX, INC.

Defendants-Cross-Appellants.

DECIDED: August 31, 2004

Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Curcuit Judge.

NEWMAN, Circuit Judge.

This patent infringement action was brought by Cardiac Pacemakers, Inc., Guidant Sales Corp., Eli Lilly and Company, and Anna Mirowski (collectively "CPI") against St. Jude Medical, Inc., Pacesetter, Inc., and Ventritex, Inc. (collectively "St. Jude"), in the United States District Court for the Southern District of Indiana.[1] The appeal relates to United States Patent No. 4,407,288, entitled "Implantable Heart Stimulator and Stimulation Method," inventors Alois A. Langer, Steve A. Kolenik, Marlin S. Heilman, Mieczyslaw Mirowski, and Morton M. Mower. We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages. We affirm the district court's decision upholding the patent term extension.

THE PATENTED INVENTION

The pumping action of the human heart occurs by electrical stimulation of various parts of the heart muscle, a complex process flowing from the nervous and other bodily systems. Heart arrhythmias result from disturbances in this process, whereby the heart may beat too slowly (bradycardia), too rapidly (tachycardia), or in an erratic, disorganized, or quivering fashion (fibrillation). Arrhythmias may occur in varying degrees. In treating such heart

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[1] Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., NO. IP 96-1718-C H/G, 2000 U.S. Dist. LEXIS 17352 (S.D. Ind. Nov. 29, 2000) (Claim Construction); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., NO. IP 96-1718-C H/G, 2002 U.S. Dist. LEXIS 14767 (S.D. Ind. July 5, 2002) (Amended Final Judgment).

abnormalities it is important to determine the form and degree of arrhythmia present, as well as to identify the section or sections of the heart in which the arrhythmia originates, such as the ventricles or the atria. The treatment must be appropriate to the specific abnormality.

The inventions subject of this lawsuit are implantable cardiac defibrillators (ICDs) that are permanently installed under the skin, and that determine abnormal cardiac activity and treat that activity by delivering electrical shocks to the heart muscle in appropriate strengths. The first successful ICDs were developed in about 1980 by a team led by the late Dr. Mieczyslaw Mirowski, an inventor of the patents in suit. In the district court two patents were in suit, for improved ICDs whereby the ICD evaluates the abnormal heart activity, determines the pattern of electrical stimulation needed to treat the type of arrhythmia exhibited by the heart, delivers the appropriate electrical pulses or shocks, and changes the pulses as necessary for optimum treatment. United States Patent No. 4,316,472 (the '472 patent) is for an improved ICD whereby the implanted device analyzes the arrhythmia, and the requisite energy levels for electrical shocks to the heart are calculated and externally programmed. Patent No. 4,407,288 (the '288 patent) is for a further improvement that continuously determines the nature of an arrhythmia as it occurs, and selectively performs multi-mode therapy. Multi-mode therapy includes administering relatively mild pacing shocks to correct mild arrhythmias, intense shocks to correct fibrillation, and shocks appropriate to correct cardioversion, which the district court defined as "the application of

non-pacing electrical pulses designed to stimulate sufficient heart tissue to correct an arrhythmia, with energy levels generally below those used for defibrillation." The cardioversion capability is basic to this appeal.

CPI charged St. Jude with infringement of claims 1 and 18 of the '472 patent and claims 4 and 13 of the '288 patent. The jury found St. Jude liable for infringement of the '472 patent, but not the '288 patent. The jury found both patents valid, and rejected St. Jude's charge that the '288 patent is unenforceable for inequitable conduct during patent prosecution. The jury awarded damages of $140 million for infringement of the '472 patent.

On post-trial motions the district court granted JMOL in favor of St. Jude on most of the issues on which CPI had prevailed in the jury verdict. The court held that the claims of both the '472 patent and the '288 patent are invalid and not infringed, and granted a conditional new trial in the event of reversal on appeal. The court also granted St. Jude's motion for sanctions based on witness misconduct, and awarded partial attorney fees to St. Jude based on Cardiac Pacemakers' failure to comply with certain discovery obligations.

No appeal is taken as to the '472 patent. CPI appeals the judgment of invalidity and non-infringement of the '288 patent, and requests reinstatement of the jury verdict. St. Jude cross appeals the court's ruling, as a matter of law, that patent term extension was properly granted.

VALIDITY

At issue are claims 4 and 13 of the '288 patent. Claim 4, and claim 1 from which it depends, state:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:
>
> (a) determining a condition of the heart from among a plurality of conditions of the heart;
>
> (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
>
> (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.
>
> 4. The method of claim 1, wherein at least one mode of operation of said

implantable heart stimulator includes cardioversion.

Claim 13, and claim 10 from which it depends, state:

> 10. An implantable heart stimulator capable of monitoring and detecting a plurality of arrhythmias, and capable of being programmed to undergo a single or multi-mode of operation corresponding to a respective arrhythmia to treat automatically the detected arrhythmia, said stimulator comprising:
>
> determining means for determining the occurrence of one of a plurality of conditions of the heart;
>
> selecting means responsive to said determining means for selecting at least one mode of operation of said implantable heart stimulator corresponding to a respective one of said plurality of conditions for automatically treating said determined conditions; and
>
> executing means for executing a sequence of events defined by said at least one mode of operation,

> whereby to treat said determined condition.
>
> 13. The stimulator of claim 10, wherein said at least one mode of operation includes cardioversion.

Granting judgment of invalidity as a matter of law, the district court ruled that Claims 4 and 13 are invalid on the ground of obviousness and for failure to disclose the best mode of making and using the invention.

Obviousness

In review of a jury verdict on the ground of obviousness, the underlying findings of fact, whether explicit or presumed as necessary to support the verdict, are reviewed for substantial evidentiary support; and the ultimate question of obviousness is reviewed for correctness in law, based on the factual premises. See Hewlett-Packard Co. v. Mustek Systems, Inc., 340 F.3d 1314, 1319 (Fed. Cir. 2003); LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001). These standards are applied by the district court upon motion for judgment as a matter of law, and again by the appellate court upon grant or denial of that motion. Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc., 248 F.3d 1303, 1309 (Fed. Cir. 2001) ("This court reviews a district court's grant of JMOL de novo and reapplies the JMOL standard.") (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 975 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996)).

CPI argues that the jury verdict must be upheld because there was substantial evidence at trial whereby a reasonable jury could have sustained the validity of the patent on the ground of obviousness, pointing out that issued patents can only be proved invalid by clear and convincing evidence. See, e.g., Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 988 (Fed. Cir. 1989) (reviewing the verdict in light of the burden of proof).

At the trial each side explained what the cited references taught, as well as the general knowledge in this field of technology at the time the invention was made. The jury was instructed that:

> The suggestion [to combine elements from separate references] can be expressly stated in a particular reference or it can be within the knowledge that was generally available to one of ordinary skill in the art.

Jury Instruction No. 46. Prior knowledge in the field of the invention must be supported by tangible teachings of reference materials, and the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself. See Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1578-79 (Fed. Cir. 1997) ("However, the record must provide a teaching, suggestion, or reason to substitute computer-controlled valves for the system of hoses in the prior art. The absence of such a suggestion to combine is dispositive in an obviousness determination."); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985)

("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.").

CPI's witnesses testified that the '288 invention was not a simple combination of known steps, but a complex solution to a difficult problem, achieved amid skepticism concerning the feasibility of producing a single implantable device that could detect and treat a wide range of heart abnormalities. St. Jude's witnesses disagreed with CPI as to the unobviousness of the combination. Evidence was presented to the jury of a long-felt but unmet need to achieve multi-mode detection and stimulus capability that included cardioversion. There was evidence that cardioversion was not treatable by existing multi-mode ICD's, and there was evidence of skepticism that such multi-mode treatment could be achieved. The jury found that invalidity of the '288 patent on the ground of obviousness had not been proved.

The district court, granting St. Jude's motion for judgment as a matter of law, found that each of the elements of claims 4 and 13 was previously known. The court cited references that described implanted cardiac devices that provided multimode therapy, although none included cardioversion therapy. The court found that cardioversion therapy was known, and found that "compelling motivation" to combine therapies in a single implanted device was provided by an article by Haft, wherein Haft explained that pacing therapy may trigger ventricular fibrillation. The district court found that Haft identified the

problem solved by the '288 patent, and concluded that it would have been obvious to design a pacing device that could defibrillate if necessary. That is, the court found that there was a known need to treat mixtures of arrhythmias, and that it would have been obvious to combine known methods of separate treatment.

Among the cited references, the district court placed weight on a British patent 2,026,870 to Duggan, as providing the motivation to combine treatments of different arrhythmias. Duggan discusses cardioversion achieved by application not of a single large shock, as in the '288 patent, but by a combination of small pacing shocks delivered simultaneously to multiple sites on the heart. CPI's expert explained that what Duggan taught was a form of pacing and not true cardioversion, and concluded that Duggan does not propose the combination of therapies provided by the '288 patent, or teach how to achieve a device that produces this combination.

We think that the district court, in granting JMOL, applied an incorrect standard to the ultimate question. Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure.

There can of course arise situations wherein identification of the problem is itself the invention. But in the case at bar the problem was well-recognized: the problem of treating complex cardiac arrhythmias. The solution of this problem, according to the trial proceedings, had not previously been achieved. It was undisputed that before the work of Dr. Mirowski and his team there was no implantable device that was capable of treating the combination of abnormal arrhythmias including cardioversion. Recognition of an unsolved problem does not render the solution obvious.

Expert witnesses for each side presented opposing opinions as to the unobviousness of the Mirowski invention. St. Jude's expert testified that in his opinion persons of ordinary skill in the relevant field would have been motivated to modify Duggan "if one felt it [cardioversion] would be better accomplished with a single high energy shock." CPI's expert testified that the Duggan reference teaches away from use of high-energy shock because Duggan is concerned only with power consumption in ICDs. St. Jude stressed the obviousness of high energy cardioversion or defibrillation shocks due to the statement in the Haft article that "antitachycardia pacing could induce fibrillation." CPI presented contrary expert opinion, stressing that no reference teaches combining cardioversion with other cardiac therapies in a single device, or states that it is feasible to do so.

It was not disputed that before the '288 invention this combination of modes of treatment had not been achieved. CPI pointed out that claim 4 requires

cardioversion, not defibrillation, and that the Haft article is concerned with fibrillation. The jury heard testimony that defibrillation shocks, not cardioversion shocks, revert fibrillation. The jury also heard testimony that defibrillation energy levels are different from cardioversion energy levels. While the jury also heard testimony that "cardioversion and defibrillation are so similar to practically be the same therapy," other witnesses disputed this position.

Whether the prior art provides the suggestion or motivation or teaching to select from prior knowledge and combine it in a way that would produce the invention at issue is a question of fact. Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000). These issues were extensively explored at the trial, including evidence of the commercial success and the interest of others in licensing the Mirowski inventions. The record contains substantial evidence whereby a reasonable jury could have reached the verdict that it would not have been obvious in March 1981 to provide an ICD that includes cardioversion. In view of this evidentiary support, the district court's grant of JMOL cannot stand. See Continental Air Lines, Inc. v. Wagner-Morehouse, Inc., 401 F.2d 23, 30 (7th Cir. 1968)[2] (the jury verdict must be sustained, even if the judge would have reached a different conclusion, if the verdict is supported by

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[2] We apply the procedural law of the regional circuit in reviewing the procedure underlying the district court's post-trial determinations. See National Presto Co. v. West Bend Co., 76 F.3d 1185, 1188 n.2 (Fed. Cir. 1996) ("On procedural matters not unique to the areas that are exclusively assigned to the Federal Circuit, the law of the regional circuit shall be applied.")

substantial evidence). The grant of JMOL is reversed, and the jury verdict is reinstated that the '288 patent is not invalid for obviousness.

Best Mode

St. Jude also presented the defense that the '288 patent is invalid for failure to set forth the best mode of practicing the invention. The jury found that the patents were not invalid on this ground. On St. Jude's post-trial motion the district court ruled that the best mode requirement was violated, and granted judgment of invalidity as a matter of law. On this question of fact, we review the evidentiary record for substantial evidence supporting the jury verdict.

A best mode violation requires that the inventor knew of and concealed a better mode than was disclosed for making and using the claimed invention. Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 588 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the claimed invention that section 112 para.1 is designed to prohibit.") (emphasis in original); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) ("in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed").

The best mode requirement differs from the enablement requirement, for failure to enable an invention will produce invalidity whether or not the omission was deliberate, whereas invalidity for omission of a better mode than was revealed requires knowledge of and concealment of that better mode.

See In re Gay, 309 F.2d 769, 772 (CCPA 1962) (best mode requirement precludes inventors "from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived"). Thus the inventor must disclose the best mode of what he claims as his invention. See also, e.g., Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1575 (Fed. Cir. 1992) ("Invalidity for violation of the best mode requires intentional concealment of a better mode than was disclosed . . . .") The question here raised relates to the best mode obligation with respect to subject matter that is not part of the invention, but that is used in conjunction therewith -- here the battery for use with these battery-powered ICDs.

St. Jude argued at trial that the inventors were required to include in the patent specification the best battery known to them at the time the patent application was filed. The inventors had asked Honeywell to develop an improved battery for use in these cardiac devices; Honeywell did so, and about four months before the '288 application was filed Honeywell published an article at the Power Sources Conference, describing the battery that it developed. The inventors testified that a battery was not part of their invention, that the Honeywell and other batteries for ICDs were known when the '288 application was filed, that various known batteries were usable in their device, that in the evolving battery art other batteries were being developed, and that they actually chose a different battery for their commercial device. The inventors stressed that their invention was not about batteries, that there was no

intent to conceal the Honeywell or any battery, and that it was not concealed. St. Jude argued that a battery was necessary to operate the device, that the Honeywell battery should have been mentioned, and that not mentioning it amounted to culpable concealment. The jury found in favor of CPI on this question.

The district court, reversing the jury verdict, held that the inventors were required to include the Honeywell battery in the patent specification, since it was the best battery then known to them. The court deemed it insufficient that Honeywell had publicly described and published the battery, and found that Honeywell's publication was in "a forum for battery specialists, not for cardiologists and inventors of ICDs." The court held that failure to include the Honeywell battery in the specification invalidated the patent on best mode grounds.

CPI states that the district court erred in law, pointing out that the invention is not about batteries, that the Honeywell battery was known, and that there was no evidence or basis for inference of intent to conceal the battery. The obligation to disclose the best mode relates to the invention that is described and claimed. See Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 1532 (Fed. Cir. 1991) ("The best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.") Subject matter that is not part of the invention that is claimed need not be included in the specification, and thus is not subject to the best mode requirement. As explained in Engel, 946 F.2d at 1532-33, "the reasons are pragmatic: the

disclosure would be boundless, and the pitfalls endless."

There was evidence before the jury that persons knowledgeable in the field of the invention would know the sources of batteries for pacemakers and related devices. There was no evidence of concealment, and the jury had evidence that the Honeywell battery was published in a publication for battery specialists. There was substantial evidence whereby a reasonable jury could have found that the best mode requirement had not been violated. The grant of JMOL on this issue is reversed, and the jury verdict is reinstated.

The Conditional New Trial

On the validity issues, the district court granted a new trial in the event of our reversal of the grant of judgment as a matter of law. We review the grant of a new trial in accordance with Seventh Circuit standards, see n.2 supra, as stated in, e.g., Billy-Bob Teeth, Inc. v. Novelty, Inc., 329 F.3d 586, 590-91 (7th Cir. 2003) ("We review a grant of a new trial for abuse of discretion. A new trial may be granted only when the verdict is against the manifest weight of the evidence.")

The jury verdicts on the issues of obviousness and best mode were not against the manifest weight of the evidence. See Continental Air Lines, 401 F.2d at 30 ("If the evidence in the record, viewed from the standpoint of the successful party, is sufficient to support the jury verdict, a new trial is not warranted merely because the jury could have reached a

different result. Neither the trial court nor this Court may substitute its judgment for that of the jury on disputed issues of fact.") (quoting Gebhardt v. Wilson Freight Forwarding Co., 348 F.2d 129, 133 (3d Cir. 1965)). Further, there was no issue of prejudicial procedural error or incorrect instruction of law. In these circumstances the conditional grant of a new trial exceeded the court's discretionary authority, and is vacated.

INFRINGEMENT

The jury found that claims 4 and 13 of the '288 patent are not infringed. Only the judgment as to claim 4, the method claim, is appealed.

CPI argues that the district court incorrectly construed claim 4 as being in the form of 35 U.S.C. §112 ¶6, and thereby incorrectly instructed the jury with respect to infringement. CPI argues that on the correct claim construction, the undisputed facts establish that the accused devices infringe claim 4. St. Jude disagrees, and also states that the misconduct of one of CPI's expert witnesses so tainted the issue of infringement that in all events a new trial of infringement is required if this court modifies the claim construction. The district court sustained the verdict of non-infringement, and granted a conditional new trial on the ground of witness misconduct.

Procedural Matters

St. Jude states that CPI failed to preserve a right to appeal the claim construction, because CPI did not make formal objection when the jury was instructed

on the claim construction. CPI responds that the claim construction was decided at the Markman hearing, and was not a proper subject of trial objection under Rule 51. St. Jude counters that all objections must be raised at the specified times during a jury trial, or they are waived. Thus St. Jude states that CPI has no right to appellate review of the claim construction that was decided at the Markman hearing and on which the jury was instructed and the trial conducted.

Rule 51 prevents a party from assigning error to an incorrect jury instruction that could have been corrected if the error had been timely raised. A party must warn the court and the opposing party that there has been an error of law. Here, the asserted error was the decision of the Markman hearing, held well before trial. The district court's construction of the claims was resolved in that decision, and was the subject of a written decision issued some six months before trial. The jury was instructed in accordance with that decision.

CPI points out that the issues of claim construction had been fully argued and briefed at the Markman hearing, and that its disagreement concerning §112 ¶6 was well known to the district court during that hearing. CPI refers to the "futility" exception, recognized by the Seventh Circuit in Chestnut v. Hall, 284 F.3d 816, 820 (7th Cir. 2002) ("A party may be excused from complying with the formalities of Rule 51 where: (1) the party's position has been previously made clear to the court; and (2) further objection would be unavailing and futile.") (citing Carter v. Chicago Police Officers M.L., 165

F.3d 1071, 1078 (7th Cir. 1998)). Cf. Ecolab Inc. v. Paraclipse, Inc., 285 F.3d 1362, 1369-70 (Fed. Cir. 2002) (applying regional circuit law to rule 51 and the futility exception).

When the claim construction is resolved pre-trial, and the patentee presented the same position in the Markman proceeding as is now pressed, a further objection to the district court's pre-trial ruling may indeed have been not only futile but unnecessary. In this case the court's claim construction resulted from a hearing at which all parties' positions were presented, and the applicability of §112 ¶6 to the claims was extensively argued. The issue was complex, and it was fully litigated to the court, who announced its decision before the jury was instructed. Objection under Rule 51 was not required to preserve the right to appeal the Markman ruling.

Claim Construction

CPI argues that the district court incorrectly construed clause (a) of claims 1 and 4:

> (a) determining a condition of the heart from among a plurality of conditions of the heart.

The court held that clause (a) is in the step-plus-function form of §112 ¶6.[3] Implementing that

[3] 35 U.S.C. §112 ¶6. An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

holding, the court ruled that clause (a) "is limited to detecting and distinguishing among arrhythmia by analyzing the outputs of rate circuitry and PDF [probability density function] circuitry," the process in the '288 specification. The jury was instructed that unless a combination of rate output and PDF circuitry or the equivalent thereof was used in the St. Jude device, the claim was not infringed.

CPI states that this claim construction is incorrect, that clause (a) is not in §112 ¶6 form and is not converted to that form simply because the preamble of the claim states that the invention is "the method comprising the steps of:". See claim 1, ante. CPI states that clause (a) simply recites a step that is part of the claimed method, and that absent the signal "step for" there is a presumption that a step does not invoke §112 ¶6. The district court disagreed, stating that if clause (a) were construed as CPI proposes, it would "allow[] CPI to claim all possible methods of detecting heart arrhythmia." Concluding that the patent would thus "sweep[] too broadly," the court ruled that clause (a) covers only the specific procedures in the specification for determining the condition of the heart, and technologic equivalents of those procedures.

CPI is correct that "claiming a step by itself, or even a series of steps, does not implicate §112 ¶6," as explained in O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1582 (Fed. Cir. 1997). Thus clause (a) was inappropriately assigned to §112 ¶6. However, removal of clause (a) from §112 ¶6 does not automatically convert it into an open-ended step without limits. A claim limitation is always

construed in light of the specification, whatever the form of the claim. See, e.g., Kinik Co. v. U.S. International Trade Comm'n, 362 F.3d 1359, 1365 (Fed. Cir. 2004) ("The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history."); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998) ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."); Grain Processing Corp. v. American Maize Products Co., 840 F.2d 902, 908 (Fed. Cir. 1988) ("All claims must be construed in light of the specification and the prosecution history.").

CPI argues that upon the correct claim construction the "determining" step is not limited to any particular procedure, because the specification makes clear that various methods may be used to determine the condition of the heart. The specification, after describing the PDF circuitry, states that "conventional logic circuitry" can be used:

> It is also to be noted that conventional logic circuitry can be provided for determining, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia. Such conventional logic circuitry can be provided either in the dedicated cardiac state evaluation circuit 34, or in one of the

> processors/controllers to be discussed below.

'288 patent, col. 10, lines 19-28 (emphasis added). CPI argues that the invention is not based on how the cardiac condition is determined, but on the treatment that is applied to that condition. CPI states that the rate plus PDF method is simply a preferred embodiment, and that this limitation should not be imported into the claim.

We conclude that the district court erred in applying §112 ¶6. Method claims necessarily recite the steps of the method, and the preamble words that "the method comprises the steps of" do not automatically convert each ensuing step into the form of §112 ¶6. Nor does the preamble usage "steps of" create a presumption that each ensuing step is in step-plus-function form; to the contrary, the absence of the signal "step for" creates the contrary presumption. The district court's claim construction is modified accordingly; the "determining" step must be construed, as for all claim steps, in light of the specification and the prosecution history. We remand to the district court for that purpose.

Infringement

CPI states that if §112 ¶6 is eliminated from the claim construction, judgment in favor of CPI is required. St. Jude states that if the claim construction is changed, at a minimum there should be a new trial of infringement.

CPI states that the jury reached the incorrect verdict of non-infringement of the '288 patent because

of the incorrect claim construction. At the trial, on the instruction that only rate-plus-PDF detection circuitry or its technologic equivalent was covered by the claim, the jury found no infringement of the '288 patent. There was extensive evidence that St. Jude did not use a rate-plus-PDF procedure. CPI did present evidence to try to prove that the St. Jude circuitry is equivalent to PDF circuitry, and St. Jude presented contrary evidence. CPI argues that on the correct claim construction, any method of determining the condition of the heart would literally satisfy clause (a), and that the question of §112 ¶6 equivalency should not have arisen. CPI argues that we can, and should, find infringement as a matter of law once we correct the district court's claim construction.

St. Jude responds that if we modify the district court's claim construction, as we have, a new trial is required so it can present evidence and argument that were not needed under the district court's original claim construction, such as whether the now-asserted scope of the claims is supported by the specification. St. Jude points out that it is entitled to jury determination of the question of infringement. We agree. It is well established that when an incorrect jury instruction -- such as an incorrect claim construction -- removes from the jury a basis on which the jury could reasonably have reached a different verdict, the verdict should not stand. See Texas Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1201 (Fed. Cir. 2002) (an erroneous instruction on claim interpretation that affects the jury's verdict on infringement is grounds for a new trial); Ecolab Inc.

v. Paraclipse, Inc., 285 F.3d 1362, 1373 (Fed. Cir. 2002) (same).

CPI is correct that a claim construction limited to §112 ¶6 equivalency would remove the possibility of finding infringement if the CPI and St. Jude circuitries were not technologically equivalents but nonetheless determined the condition of the heart. We conclude that a new trial of infringement is required, for the question of infringement was not explored on the purportedly less restrictive claim construction that avoids §112 ¶6. That question requires findings and conclusion by the trier of fact.

The Sanctions for False Testimony

The district court held that if a new trial of infringement is required, CPI should pay St. Jude's attorney fees for the new trial because of the misconduct of a CPI infringement expert. CPI argues that if the new trial of infringement is based solely on the district court's erroneous claim construction and is unrelated to the false testimony of the witness,[4] the contingent sanction of attorney fees should be vacated.

The new trial here ordered is unrelated to the witness' deception; indeed, the jury rendered a verdict of noninfringement of the '288 patent despite

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[4] The witness had concealed contradictory testimony that he had given in a related case. CPI has paid and is not appealing the sanctions already imposed, for St. Jude's attorney fees and expenses associated with the false testimony.

his contrary testimony. Therefore the conditional sanction is vacated.

DAMAGES

The jury awarded damages of $140 million for infringement of the '472 patent. The district court granted JMOL of non-infringement of the '472 patent; that judgment is not appealed. CPI asks that the damages award be applied to the '288 patent, arguing that the same evidence was presented for both patents without distinction. St. Jude responds that the damages award cannot be shifted to a patent that the jury found not to be infringed, and argues that it is excessive in any event.

We conclude that it is inappropriate to shift the jury's damages award. The damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand.

PATENT TERM EXTENSION

St. Jude by cross appeal challenges the district court's ruling that the term of the '288 patent was properly extended under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act). The Act permits a patentee to obtain an extension of the patent term if marketing of the patented product was delayed due to federal regulatory review:

> 35 U.S.C. §156(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be

extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if --

. . . .

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5) (A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent;

(Emphasis added.)

Questions of statutory interpretation receive plenary review on appeal. Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003); Hosiden Corp. v. Advanced Display Manufacturers, 85 F.3d 1561, 1567 (Fed. Cir. 1996). The question here arises because the CPI device is not the first device covered by the '288 patent to receive FDA approval. CPI had granted licenses to two other companies for defibrillators, however, term extension was not requested based on the licensees' devices. In CPI's application for extension based on its PRx defibrillator, CPI stated that licenses had been granted for two other defibrillators covered by the '288 patent, the Ventritex V-100 and the Medtronic PCD, for each of which the licensee had obtained FDA approval. The Patent and Trademark Office and the FDA granted the extension based on the PRx approval period.

The district court held that extensions under subsection (5)(A) need not be based on the first FDA-approved medical device covered by the patent, but must be based on "the first permitted commercial marketing or use of the product" that is the basis of the application. The district court stated that the statute gives patentees a choice "in matching up products and the patents for which they seek extensions."

St. Jude argues that the district court erred, and that CPI's PRx defibrillator cannot be a basis for extension of the term of the '288 patent, no matter how independent its FDA approval procedure, because the Ventritex and Medtronic ICDs were previously approved and commercialized. CPI

responds that when various devices, all requiring separate regulatory approval, are covered by the same patent, it suffices that the particular device on which the application for extension is based is covered by the patent and is subject to regulatory review, and that only one extension per patent is available.

The district court agreed with CPI, and held that §156(a)(5)(A) does not require that the device on which the extension is based is the first approved product within the claims of the patent. The court stated: "The court should not read into subparagraph (a)(5)(A) the limiting requirement that Congress imposed so clearly in writing subparagraph (a)(5)(B), but only for method patents primarily using recombinant DNA technology." The district court relied on the fact that §156(a)(5)(A) refers to "marketing or use of the product" that the patentee has selected, whereas subparagraph (a)(5)(B), for DNA technology, refers to "the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent." In Brown v. Gardner the Court cautioned that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." 513 U.S. 115, 120 (1994) (quoting Russello v. United States, 464 U.S. 16, 23 (1983)).

St. Jude argues that the comparison between subparagraphs (a)(5)(B) and (a)(5)(A) is strained, and does not support the distinction drawn by the district

court. St. Jude criticizes the weight the court gave to the change in text from "the" to "a," and directs attention to Fisons PLC v. Quigg, 876 F.2d 99, 100-01 (Fed. Cir. 1989), wherein this court held that a drug-patent extension must be based on the first FDA approval of the active ingredient of the patented product because, under the definition in §156(f)(2), the active ingredient is the approved "product." Thus in Fisons the court held that subsequent extensions were not available for subsequent products using the same active ingredient that was the basis of the first extension, implementing the principle that only one extension is available per approved product. See Fisons, 876 F.2d at 100 ("[I]t follows that because Fisons' patented new products containing cromolyn sodium did not qualify as the first permitted commercial marketing or use of the active ingredient cromolyn sodium, extensions of the patent term for the subject patents were not permissible.")

The district court agreed that only one extension was available, but held that the patentee was not required to rely on a licensee's version of the device as the basis for the extension. The legislative history supports this interpretation, for as originally proposed §156(a) required that extensions "be granted only for the first approved product," H.R. Rep. No. 98-857, pt. 1, at 38 (1984), but that provision was removed from the legislation before enactment. See Gulf Oil Corp. v. Copp Paving Co., 419 U.S. 186, 200 (1974) (Congress's failure to enact a proposed version of a statute "strongly militates against a judgment that Congress intended a result that it expressly declined to enact.")

The decision that extension was available based on CPI's PRx defibrillator is affirmed.

Lapse Due to Incorrect Payment of Maintenance Fees

St. Jude also argues that the '288 patent expired when CPI did not pay the correct maintenance fee, and that although the payment was later corrected and accepted by the Patent and Trademark Office, the patent must be deemed to have expired with the error, at least for purposes of term extension:

> 35 U.S.C. §156(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section . . . if --
>
> (1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension.

The district court held that, in accordance with statute and regulation, the error had been corrected and the patent had not expired.

CPI points out that the statute provides for late payment and for correction of error without loss of rights, and that this was achieved. 35 U.S.C. §41(c)(1) states:

> §41(c)(1) If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall

> be considered as not having expired at the end of the grace period.

St. Jude argues that this beneficence does not affect the requirement of §156(a)(1) that the application for extension must be submitted before patent "expiration," and that the later revival of an expired patent does not overcome this stricture.

When the '288 patent was issued in 1983, the patentee was a "small entity" and qualified for reduced fees under 35 U.S.C. §41(h)(1). From 1987 to 1998 the patentee paid the maintenance fees at the reduced rate applicable to small entities. However, in 1985 the '288 patent was non-exclusively licensed to a large entity, triggering the regulatory provision whereby the small entity status is lost to the patentee. See 37 C.F.R. §1.9(d) (1985) (providing that small entity status is lost when any rights are licensed to any concern that does not qualify as a small entity). Meanwhile the patent was licensed to Eli Lilly & Company, which does not qualify as a small entity. In 1998 CPI advised the PTO of the error, stated that the erroneous payments as a small entity were made in good faith, and tendered the additional sums due and statutory penalties. The PTO accepted the late payments on October 16, 1998.

St. Jude argues that the patent expired in 1987 when the first incorrect maintenance fee was paid. However, the statute is explicitly contrary. See 35 U.S.C. §41(c)(1) ("If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.") A similar issue was

considered in Ulead Systems, Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139 (Fed. Cir. 2003), wherein this court confirmed that the patent did not expire.

The district court correctly held that the '288 patent did not expire, and that the application for term extension was validly submitted. The decision on this issue is affirmed.

Costs

Each party shall bear its costs.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

Appendix E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

CARDIAC PACEMAKERS, INC.,
GUIDANT SALES CORPORATION,
MIROWSKI FAMILY VENTURES, LLC,
and ANNA MIROWSKI,

Plaintiffs,

v.

Case No.
1:96-cv-1718-DFH-TAB

ST. JUDE MEDICAL, INC., and
PACESETTER, INC.,

Defendants.

ENTRY ON POST-REMAND MOTIONS FOR SUMMARY JUDGMENT

Introduction

This long-running patent infringement lawsuit is before the court on motions for summary judgment on the issues of infringement and anticipation. As explained in detail below, the court finds as a matter of law that defendants' devices infringe the one method claim still at issue. The court also finds as a matter of law that the remaining method claim, under the broader claim construction applied after the Federal Circuit's remand, is invalid as anticipated by the prior art. The court is entering

final judgment for defendants.

Implantable cardiac defibrillators ("ICDs") are sophisticated electrical devices that can deliver life-saving therapy to correct dangerous and even fatal abnormal heart rhythms. Plaintiffs Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively, "CPI") sued defendants St. Jude Medical, Inc., and Pacesetter, Inc. (collectively, "St. Jude") in 1996 for infringing numerous claims of four United States patents relating to ICDs. Plaintiffs voluntarily dismissed claims under one patent before trial, and the court on summary judgment held invalid the relevant claims of another patent. The Federal Circuit affirmed that decision in an appeal of a partial final judgment on that issue. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 296 F.3d 1106 (Fed. Cir. 2002).

In 2001, the case went to trial on four claims of the two remaining patents. The jury found that one patent (U.S. Patent No. 4,407,288) was valid but not infringed. The jury found that the other (U.S. Patent No. 4,316,472) was valid and infringed, and awarded CPI damages of $140 million. This court later granted judgment as a matter of law to St. Jude on all claims, including a finding that the relevant claims of the '288 patent were invalid as obvious in light of the prior art. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 2002 WL 1801525 (S.D. Ind. 2002). To the court's surprise, CPI did not appeal the portion of the judgment setting aside the $140 million damage award on the '472 patent. Instead, CPI appealed primarily on the basis of a claim

construction issue on one claim, claim 4, of the '288 patent that the jury found was not infringed, and appealed this court's finding of invalidity for obviousness, among several other issues.

The Federal Circuit affirmed in part and reversed in part. The Federal Circuit agreed that the construction of claim 4 needed a fresh look, though the Federal Circuit did not itself decide how the claim should be construed. The Federal Circuit remanded for reconsideration of the construction of the one claim and a new trial on that one claim. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371, 1381-82 (Fed. Cir. 2004). The Federal Circuit also held that this court erred in overturning the jury's finding that claim 4 of the '288 patent was valid and not obvious. *Id.* at 1378.

After remand, the parties staked out their positions in new claim construction briefs on claim 4, as well as a series of motions for summary judgment. The court construed claim 4 and addressed several other issues, but not all of the pending motions for summary judgment. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 418 F. Supp. 2d 1021, 1031 (S.D. Ind. 2006). The Federal Circuit denied CPI's petition for a writ of mandamus, which had argued that this court was violating the Federal Circuit's mandate by leaving open for consideration on remand several issues pursued by St. Jude. *In re Cardiac Pacemakers, Inc.*,183 Fed. Appx. 967 (Fed. Cir. June 2, 2006).[1]

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[1] This case has actually been before the Federal Circuit four

The parties then tried to settle the case. On July 31, 2006, the parties announced an interesting partial settlement that substantially narrowed the issues and limited the potential damages. See Remand Docket No. 181, Exs. A & B (SEC Form 8-K's). Plaintiffs agreed not to pursue lost profits, agreed to cap any royalty at no more than three percent of net sales revenues from infringing sales, and agreed not to pursue prejudgment interest. Defendants agreed not to pursue a fraud claim or an inequitable conduct defense based on certain alleged misconduct, and agreed not to pursue any claim for attorney fees. The parties later informed the court that continued settlement negotiations had reached an impasse so that the court should return to the remaining summary judgment motions. Each side filed a short statement commenting on the effects of the court's claim construction interpretation and their partial settlement on the issues presented by the motions. Remand Docket Nos. 198 & 202. More recent settlement efforts have also reached an impasse. The court now addresses the pending motions as follows.

I. *Infringement Issues*

The court's March 1, 2006 claim construction ruling on remand narrowed the issues on

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times. In addition to the three decisions cited in the text, the Federal Circuit held in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 144 Fed. Appx. 106 (Fed. Cir. 2005), that Seventh Circuit Rule 36 did not apply so as to require that the case be assigned to a new district judge for the new trial. In light of the parties' failure to reach a complete settlement, at least one more visit to the Federal Circuit seems likely.

infringement considerably. The undisputed facts before the court show that the accused St. Jude devices perform all steps of the '288 patent's claim 4 method when the devices actually carry out the form of therapy known as "cardioversion" (as distinct from both pacing therapy and defibrillation). In other words, plaintiffs are entitled to partial summary judgment on that question. St. Jude has had ample opportunity to distinguish the operation of its devices from the newly-construed version of claim 4, and it has not done so. CPI's motion for summary judgment on infringement is granted to the extent that the actual operation of those devices to deliver cardioversion therapy infringes claim 4.

That finding does not go so far as to hold defendants liable for infringement, however. CPI's decision to limit its case now to the claim 4 method means that CPI must show such actual use of the St. Jude devices, see 418 F. Supp. 2d 104142, and it must show that St. Jude induced any infringement that might be shown. Those are issues as to which neither side has shown it is entitled to summary judgment.[2]

CPI has also asked the court to rule on a question that may be relevant to damages. The issue

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[2] St. Jude has recently filed an additional motion for summary judgment based on the Federal Circuit's decision in *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006), holding that a claim for knowing inducement of patent infringement by another under 35 U.S.C. § 271(b) requires proof of specific intent to infringe. That motion has not yet been briefed. In light of the court's decision on the anticipation defense discussed below, the court does not reach the specific intent issue.

is whether St. Jude had available to it a non-infringing alternative design under U.S. Patent No. 4,880,005, a patent for an ICD device that would have had the capacity to learn from its experience in treating arrhythmias. Claim 4 of the '288 patent requires the step of "selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition." Under the '005 patent, the device's choice of therapy would depend on the patient's history with the device. For example, a device might be programmed initially to respond to a certain form of ventricular tachycardia (rapid heart rate) with pacing shocks, to be followed by more powerful cardioverting shocks if the pacing is not successful. But the device could also be programmed to respond to the second or later similar episodes of tachycardia by skipping the previously unsuccessful therapy of pacing shocks and going straight to the cardioverting shocks. Defendants argue that a device programmed in this manner to learn from its experience in treating a patient's condition does not provide "a *unique* sequence of events corresponding to said determined condition," as required by claim 4 of the '288 patent.

CPI argues that this question is too hypothetical at this stage and that there are issues of fact as to whether the '005 form of programming was in fact available to St. Jude during the period of alleged infringement. The court agrees with CPI that the issue is not yet suitable for a definitive ruling on summary judgment. There are disputed factual issues as to whether and exactly when a design under the '005 patent would have been available to St. Jude.

Accordingly, CPI's motion for summary judgment on infringement (Remand Docket No. 72) is granted to the extent that any proven actual use of the St.Jude devices for cardioversion therapy infringes claim 4 as a matter of law. CPI's motion is denied in other respects, without reaching the specific intent issue raised recently. St. Jude's motion for summary judgment on the issue of infringement (Remand Docket No. 85) is also denied.

II. *Anticipation*

A patent claim is invalid as anticipated if every limitation in a claim is found in a single prior art reference, either explicitly or inherently. See *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (affirming summary judgment of invalidity based on anticipation); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (same). The first step of an anticipation analysis is claim construction; the second step is a comparison of the construed claim to the prior art. *Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000). Anticipation must be shown by clear and convincing evidence. *Id.* To be anticipating, a prior art reference must disclose "each and every limitation of the claimed invention[,] . . . must be enabling[,] and [must] describe . . . [the] claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." *Id.* This court has already construed claim 4 of the '288 patent.

St. Jude has moved for summary judgment (Remand Docket No. 80) on the ground that claim 4 of

the '288 patent is invalid as anticipated by at least two prior art references based on work done by Medtronic scientists in the 1970s. (Medtronic Corporation is another major competitor in the ICD field.) As the history of this case has shown in painstaking detail, by the time the research was done that led to the application for the '288 patent, the field of implantable cardiac defibrillators was what might be called a "crowded art." Whether the applicants could thread their way through the prior art to find something truly novel presented quite a challenge.

A. *Ability to Consider Anticipation*

As a threshold matter, CPI argues that claim 4 could not possibly have been anticipated, and that the issue is no longer even open for debate, because the Federal Circuit reversed this court's earlier judgment as a matter of law to the effect that claim 4 was invalid as obvious. See 381 F.3d at 1378. At first glance, of course, it seems that if the invention of the claim was not obvious under the prior art, it also could not be invalid for anticipation.

CPI's arguments on this point fail to take into account the critical role that the revised claim construction plays. The Federal Circuit's opinion explicitly opened the door to consideration of validity issues, at least to the extent they were based on a revised construction of claim 4. See 381 F.3d at 1382-83 (agreeing with St. Jude's argument that modified claim construction would require a new trial so that St. Jude could present evidence and arguments not needed under original claim construction, such as

whether the claim is supported by the specification). In denying CPI's petition for a writ of mandamus, the Federal Circuit wrote about its prior decision:

> To the extent that our opinion may not, despite our attempts, have been sufficiently clear, we repeat that we "remand[ed] for a new trial of infringement and reassessment of damages," *Cardiac Pacemakers*, 381 F.3d at 1374, including reconstruction by the district court of the "determining" provision in light of our ruling that section 112 ¶ 6 did not apply, *Id.* at 1382. We also recognized that a new claim construction may raise directly related new issues, "such as whether the now-asserted scope of the claims is supported by the specification," *Id.* at 1383.
>
> All the other issues on appeal were finally decided, and are not subject to reopening on remand.

183 Fed. Appx. 967.

This court would not and could not revisit the issue of obviousness as decided by the Federal Circuit. However, the revised construction of claim 4 advocated by CPI and adopted by this court has substantially broadened the scope of the claim. The earlier construction had meant that claim 4 covered only methods that determine a condition of the heart by evaluating both the heart rate and what was described as a probability density function, or "PDF." As a result, some of the relevant prior art was readily distinguishable from claim 4 under this

court's earlier construction, based on the absence of PDF in the determining step.

The revised construction sought by plaintiffs eliminates that limitation in terms of how the condition of the heart is determined. 418 F. Supp. 2d at 102830. Claim 4, properly construed after the Federal Circuit's remand, covers methods that use a wide variety of methods to determine the condition of the heart, including methods that measure only the heart rate. Under the broader construction of claim 4, this court respectfully concludes that the anticipation defense is, in the words of the Federal Circuit, a "directly related new issue." By successfully arguing for a broader construction of claim 4, CPI has opened the door for St. Jude to try to show that prior art in fact included *all* the elements of claim 4. If an item of prior art in fact shows all the elements of claim 4, then one need not address the more complex issues involved in the question of obviousness, such as those addressed at an earlier stage.[3]

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[3] For example, where the prior art "teaches away" from the invention claimed in the new patent, that fact will be highly relevant to the issue of obviousness. See *Cardiac Pacemakers, Inc.*, 381 F.3d at 1377 (in discussion of obviousness issue, citing evidence that Duggan '870 "teaches away from use of a high-energy shock"). In considering the issue of anticipation, however, if the prior art discloses all the elements of the newly-claimed invention, the fact that the prior art might "teach away" from the new invention does not matter. *E.g., Upsher-Smith Laboratories, Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1323 (Fed. Cir. 2005).

B. *Claim 4 of the '288 Patent*

Before delving into the details of the prior art, it is worth recalling that the issue here is not whether some aspects of the '288 patent were novel and useful. Nor is the issue whether the inventors and the patent made an important contribution to the development of more sophisticated and effective ICDs. The plaintiffs have chosen to hang all that remains of their case on *just one claim*, claim 4, so the focus must remain on whether *just that claim* represents a novel invention.

Claim 4 of the '288 patent, including Claim 1 from which it depends, claims:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:
> (a) determining a condition of the heart from among a plurality of conditions of the heart;
> (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
> (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

> 4. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.

'288 patent, col. 21:9-32.

C. *Denniston '795*

As properly construed now, the undisputed facts show that claim 4 of the '288 patent was anticipated by United States Patent No. 3,805,795, issued to Rollin H. Denniston on April 23, 1974.

Denniston '795 described an implantable electronic system that detects any of a variety of arrhythmias and automatically cardioverts the heart. Def. Ex. 23, col. 2:59 – col. 3:16. The device was capable of delivering both cardioverting shocks and the lower energy pacing shocks. See *id.* at col. 4:24-27 (intravascular lead can also be used to sense heart conditions and to transmit pacing pulses to the heart).

Working through the elements of claim 4 of the '288 patent, the first element is a "method of heart stimulation using an implantable heart stimulator." Denniston '795 clearly meets that element: "the system including both electrodes may be totally and completely implanted under the skin of the patient." Ex. 23, col. 3:12-14.

The next element is that the stimulator is "capable of detecting a plurality of arrhythmias." The Denniston device is capable of detecting bradycardia (slow heart rate) that requires pacing pulses. Ex. 23, col 4:24-27; col. 7:26-32 (R wave amplifier operates in

same manner as those commonly used in demand pacer for heart, adapted to discriminate between normal and abnormal heart functions). The Denniston device is also capable of detecting ventricular tachycardia and ventricular fibrillation and other types of tachyarrhythmias. Col. 3:6-11; col. 3:36-51. Denniston also described other means for using the system to detect and discriminate among other types of arrhythmias. Col. 19:32-42.

The next element of claim 4 is that the device must be "capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia." As to multi-mode operation, the intravascular lead that is used to deliver cardioversion shocks "is also capable of being used for sensing heart conditions requiring heart pacing and for transmitting pacing pulses to the heart." Col. 4:24-27. The cardioversion therapy could be delivered only after a normal heart rate is absent for a pre-set period of time, on the order of 15 to 20 seconds, col. 3:65-67, during which time pacing pulses could first be applied. The Denniston device therefore is capable of multi-mode operation. As to single-mode operation, the lead that could be used to transmit pacing pulses could also be instructed not to deliver such pulses, so that only the single mode of cardioversion would be available to treat an arrhythmia. As Dr. Mihran testified at the 2001 trial: "if one were to have Denniston implanted and wanted the single mode of operation only, then the pacing function could be turned off. So that would be a single mode operation. If it was left on, then it would perform the multi-mode operation then." Tr. 3166-67 (June 28, 2001); see also *Cardiac*

Pacemakers, Inc., 2000 WL 1765358, *29 (claim construction ruling explaining that programming for multi-mode operation also allows for programming for single-mode operation). The Denniston device is capable of being programmed to deliver only pacing therapy, also. If pacing pulses restore normal heart operation, then the device will not deliver cardioversion shocks. Col. 3:53-55.

The next element of claim 4 is the step of "(a) determining a condition of the heart from among a plurality of conditions of the heart." As noted above, the Denniston device is capable of distinguishing among different arrhythmias. It also performs the determining step by detecting, for example, the absence of a heartbeat using an EKG sensor and a heart contraction sensor, col. 3:36-51, and also determining when a normal heartbeat is restored after delivery of therapy.

The next element of claim 4 of the '288 patent is the step of "(b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition." The Denniston device also performs this step. For example, if the device senses the absence of a heartbeat, the Denniston device can select pacing pulses alone, pacing pulses followed by cardioversion if needed, or only cardioversion. See Col. 3:52 – 4:7; col. 4:24-27; Tr. 2975-77, 2990, 3125-26, 3163-67.

The next element of claim 4 of the '288 patent is the step of "executing said at least one mode of operation of said implantable heart stimulator

thereby to treat said determined heart condition." The Denniston device carries out the executing step by actually delivering the selected therapy in response to the detected arrhythmia, such as by delivering pacing pulses and/or cardioversion shocks.

The Denniston '795 patent thus discloses all elements of claim 1 of the '288 patent. Claim 4 requires the additional element that "at least one mode of operation of said implantable heart stimulator includes cardioversion." The Denniston device also includes the cardioversion mode of operation, teaching the use of a first cardioversion shock of 700 volts, for example, followed by a stronger shock of 900 volts if the first shock does not restore a normal rhythm. Col. 18:39– 19:15.

In its opening brief for summary judgment on anticipation, St. Jude showed in detail how each of these elements was taught in Denniston. In arguing against a finding of anticipation on the merits, CPI argued in its brief only that Denniston did not describe an "externally programmable" device. CPI relies on trial testimony from Dr. Mihran, an expert for St. Jude:

> Q: Denniston can't be programmed externally, correct?
>
> A: Denniston does not describe a programming operation, that's correct.

Tr. 3163. The question was specific to external programming. Claim 4 of the '288 patent is not so limited to only external programming. The question

and answer therefore do not present a genuine issue of material fact that would bar summary judgment.

Denniston '795 clearly shows a device that is programmable for different levels of cardioversion energy. Denniston explained: "The resistive values of transistors 466, 468 and 474 may be selected, so that the electrical line 35 voltage required to render PUT [programmable unijunction transistor] 470 conductive is 700 volts when transistor 478 is nonconductive, and 900 volts when transistor 478 is conductive." Col. 14, ll. 30-34. In columns 18 and 19, Denniston described the operation of the device to provide first a 700 volt pulse and then if needed a second and even third pulse at 900 volts.

At the hearing on the anticipation motion for summary judgment, CPI raised a host of new arguments regarding Denniston for the first time. CPI argued that the "capable of being programmed" limit in claim 1 is limited to *external* programming. This argument was made too late, and is without merit in any event. In this respect, claim 1 was drafted broadly, without this additional limitation of being externally programmed. In fact, the '288 patent claims were drafted so as to distinguish between the broader "programming" and the narrower, more specific "external programming." Dependent claim 7, which is also dependent on claim 1, adds to the claimed method the further step of "*externally* programming said microprocessor-controlled implantable stimulator with respect to said at least one mode of operation thereof." (Emphasis added.)

In light of this careful drafting, it would be a mistake to graft onto the deliberately broader language of claim 1 the additional limitation that the method would need to include external programming. Courts construing patents presume that there is "a difference in meaning and scope when different words or phrases are used in separate claims." *E.g.*, *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998); see also *Cardiac Pacemakers*, 2000 WL 1765358, *16 (adopting CPI's argument for claim differentiation), citing *Karlin Technology, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 972 (Fed. Cir. 1999) ("limitations stated in dependent claims are not to be read into the independent claim from which they depend"). CPI points out correctly that the principle of claim differentiation is not inflexible, citing *Power Mosfet Technologies, L.L.C. v. Siemens AG*, 378 F.3d 1396, 1409-10 (Fed. Cir. 2004); see also *Comark Communications*, 156 F.3d at 1187 (rule is not "hard and fast"), but in light of the critical role of claim language, the principle of claim differentiation remains an essential tool for all but the most unusual cases.

Throughout the long history of this case, CPI has repeatedly argued against the error of narrowing broad claim language by reading in limitations from the specification, such as limiting broad claims of the '472 patent to only the atrial conditions addressed in the specification, limiting cardioversion to the manual cardioversion in the specification, or limiting the determining step of the '288 patent to use of the PDF method in the specification. See 418 F. Supp. 2d at 1029; 2000 WL 1765358, *4-6, *14. The use of

the broad term "programmed" in claim 1 did not create an ambiguity requiring clarification. Instead, the use of that broad term reflected a deliberate decision to draft a broad independent claim, which then became the foundation for a host of narrower and more specific dependent claims, including claim 7, which expressly required external programmability.

At the hearing, CPI also sought improperly to raise a number of other issues regarding Denniston for the first time. CPI's brief in opposition to summary judgment on anticipation asserted at page 1: "Plaintiffs dispute alleged facts in numbered paragraphs C1, C4, C7, C14, D1-D3, D5-15, E1-E3, and E5-E10 in St. Jude's brief." Docket No. 121 at 1, ¶ 1. The only other specific point that CPI raised to dispute any of the "C" paragraphs (which address the Denniston '795 patent) was the quoted question and answer from Dr. Mihran at trial on the issue of external programming.

CPI's conclusory assertion that it disputed the listed paragraphs was not sufficient to present a genuine issue of material fact. This court's Local Rule 56.1 includes requirements for a party's opposition to summary judgment:

> The brief shall include a section labeled "Statement of Material Facts in Dispute" which responds to the movant's asserted material facts by identifying the potentially determinative facts and factual disputes which the nonmoving party contends demonstrate that there is a dispute of fact precluding

> summary judgment. These facts shall be supported by appropriate citations to discovery responses, depositions, affidavits, and other admissible evidence either already in the record or contained in an appendix to the brief.

S.D. Ind. Local Rule 56.1(b). Local Rule 56.1(e) further provides in relevant part:

> For purposes of deciding the motion for summary judgment, the Court will assume that the facts as claimed and supported by admissible evidence by the moving party are admitted to exist without controversy, except to the extent that such facts are specifically controverted in the opposing party's "Statement of Material Facts in Dispute" by admissible evidence. . . . * * * The court has no independent duty to search and consider any part of the record not specifically cited in the manner described in sections (a) and (b) above.

Summary judgment practice has become such a big part of federal civil practice that compliance with these procedural requirements, and in particular the requirement to guide the court toward the specific evidence and issues requiring a trial, has become essential for district courts trying to manage their dockets. The Seventh Circuit has repeatedly upheld the enforcement of this court's Local Rule 56.1 and similar local rules used to manage summary judgment practice by ensuring that issues are presented clearly and squarely, without leaving the district court to wander through the record in search of the evidence the non-moving party might be

relying upon. Among many examples that could be cited, see, *e.g.*, *Ammons v. Aramark Uniform Services, Inc.*, 368 F.3d 809, 81718 (7th Cir. 2004) (affirming summary judgment, collecting many cases on this point, and finding that district court properly struck attempts to raise factual disputes without specific citations to evidence: "Citations to an entire transcript of a deposition or to a lengthy exhibit are not specific and are, accordingly, inappropriate. A court should not be expected to review a lengthy record for facts that a party could have easily identified with greater particularity."); *Smith v. Lamz*, 321 F.3d 680, 683 (7th Cir. 2003) (affirming summary judgment where non-moving party failed to support factual assertions with specific citations to evidence: "A district court is not required to 'wade through improper denials and legal argument in search of a genuinely disputed fact.'"), quoting *Bordelon v. Chicago School Reform Bd. of Trustees*, 233 F.3d 524, 529 (7th Cir. 2000); *Brasic v. Heinemann's, Inc.*, 121 F.3d 281, 285 (7th Cir. 1997) (affirming summary judgment: "It is not our task, or that of the district court, to scour the record in search of a genuine issue of triable fact. We rely on the nonmoving party to identify with reasonable particularity the evidence that precludes summary judgment."), quoting *Richards v. Combined Ins. Co. of America*, 55 F.3d 247, 251 (7th Cir. 1995); *Herman v. Chicago*, 870 F.2d 400, 404 (7th Cir. 1989) ("A district court need not scour the record to make the case of a party who does nothing."); see also *Corley v. Rosewood Care Center, Inc.*, 388 F.3d 990, 1001 (7th Cir. 2004) (enforcing parallel requirement for citations to record in appellate briefs: "Corley has

failed miserably and we will not root through the hundreds of documents and thousands of pages that make up the record here to make his case for him.").

St. Jude properly supported its motion for summary judgment on anticipation with specific and detailed arguments supported by specific and detailed citations to the relevant evidence. The conclusory and unsupported list in CPI's brief of the paragraphs that it disputed was not sufficient to preserve any issue. A "mere disagreement with the movant's asserted facts is inadequate if made without reference to specific supporting material." *Smith v. Lamz*, 321 F.3d at 683, citing *Edward E. Gillen Co. v. City of Lake Forest*, 3 F.3d 192, 196 (7th Cir. 1993). The only argument that CPI developed on the merits was the argument that Denniston '795 was not programmable, supported only by the evidence that it was not externally programmable, which is beside the point for reasons explained above.

At the hearing on February 13, 2007, CPI argued for the first time that Denniston '795 is not programmable for multi-mode operation, that it does not provide multi-mode operation, and that it does not provide a unique sequence of therapy for a selected arrhythmia. These arguments were not raised at all in CPI's brief. It is not fair to St. Jude or to the court to present them orally for the first time at the hearing on the motion, and without complying

with this court's Local Rule 56.1(b). The court does not consider these forfeited arguments.[4]

D. *Duggan '870*

Duggan '870 is United Kingdom Patent Application 2,026,870. Duggan '870 described an implantable cardiac stimulator controlled by a microprocessor. It was capable of delivering pacing-level shocks to single sites in the atrium and ventricle in sequence. That therapy could be followed by simultaneous delivery of pacing-level shocks to multiple sites in the heart muscle. Dr. Mihran described such simultaneous pacing-level shocks as a form of cardioversion. Other prior art from Medtronic also described the same therapy – simultaneous delivery of pacing-level shocks to multiple sites in the heart muscle – as "cardioversion." See Rockland '140 (Def. Ex. 27, col. 1, ll. 41-68); Funke '226 (Ex. 28).

In its motion for summary judgment, St. Jude explained in detail in Paragraphs D4 through D12 how Duggan '870 taught all elements of the method of claim 4 of the '288 patent. CPI's response brief stated without elaboration that it disputed paragraphs "D1-D3, D5-15" relating to Duggan. As

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[4] To illustrate further the problems with CPI's response to the motion for summary judgment, CPI announced at the hearing that its statement that it disputed "paragraphs C1, C4, C7, C14" relevant to Denniston '795 included a typographical error, and that it should have said it disputed "paragraphs C1, C4, C7 *through* C14." Because CPI failed to provide specific support for its attempt to dispute any of these paragraphs, apart from the external programming theory, St. Jude and the court had no other sign before the hearing that CPI was attempting to dispute paragraphs C8 through C13.

explained above, such a conclusory and unsupported response does not properly raise any issue of material fact. A "mere disagreement with the movant's asserted facts is inadequate if made without reference to specific supporting material." *Smith v. Lamz*, 321 F.3d at 683.

The only specific issue that CPI raised regarding Duggan was whether it taught "cardioversion," citing specifically the trial testimony of defense experts Dr. Mihran and Dr. Rickards. During the 2001 trial, Dr. Mihran acknowledged on cross-examination that the energy levels described in Duggan '870 were the lower levels associated with pacing rather than cardioversion. Tr. 3134-36. He did not concede that Duggan '870 failed to teach cardioversion. His answer that was specific to the energy levels was consistent with Dr. Mihran's description of Duggan '870 as teaching a form of cardioversion. And his answer certainly cannot erase the undisputed fact that the prior art described the Duggan '870 therapy as a form of cardioversion. See *Cardiac Pacemakers, Inc.*, 381 F.3d at 1377 ("Duggan discusses cardioversion achieved by application not of a single large shock, as in the '288 patent, but by a combination of small pacing shocks delivered simultaneously to multiple sites on the heart.").

CPI also relies on Dr. Richards' testimony at trial. He agreed that Duggan '870 did not have the element of a cardioverter. Tr. 1955-56. He also answered a negative question that produced an ambiguous answer:

Q: Duggan is not a cardioverter?

A: No.

Id.

Does this produce a genuine issue of material fact? The prior art described the Duggan '870 method of multiple simultaneous pacing-level shocks as "cardioversion." There is no indication in the '288 patent that the term cardioversion in claim 4 was used in any narrow or specialized way that would exclude the Duggan/Medtronic form of cardioversion through multiple simultaneous shocks. (One might only consider the possibility of the shoe being on the other foot. If the '288 patent had issued before the Duggan '870 patent, and if CPI were accusing someone who was practicing the Duggan '870 invention of infringing the '288 patent, the argument that the multiple pacing-level shocks described in the prior art as cardioversion was not "cardioversion" under the '288 patent would not have much traction.)

Accordingly, the only specific issue raised by CPI presents no genuine issue of material fact. Duggan '870 anticipated claim 4 of the '288 patent by disclosing every element of claim 4.

Conclusion

In an effort to pursue its infringement claims through this "crowded art," CPI ultimately chose to rest its case on only claim 4 of the '288 patent. The undisputed facts show that St. Jude's accused devices infringe that claim when they are actually used to deliver the therapy of cardioversion. CPI is entitled to summary judgment on that issue. The undisputed facts also show, however, that both

Denniston '795 and Duggan '870 anticipated the broader claim 4 as newly construed on remand from the Federal Circuit. The court therefore grants St. Jude's motion for summary judgment on the ground of anticipation (Docket No. 80). All other pending motions not addressed specifically in this entry are denied as moot. The court will enter final judgment for defendants accordingly.

So ordered.

Date: March 26, 2007

/s/ David F. Hamilton
DAVID F. HAMILTON, JUDGE
United States District Court
Southern District of Indiana

Appendix F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

CARDIAC PACEMAKERS, INC.,
GUIDANT SALES CORPORATION,
MIROWSKI FAMILY VENTURES, LLC,
and ANNA MIROWSKI,

Plaintiffs,

v. Case No. 1:96-cv-1718-DFH-TAB

ST. JUDE MEDICAL, INC., and
PACESETTER, INC.,

Defendants.

ENTRY AFTER REMAND ON CLAIM CONSTRUCTION AND MOTIONS FOR PARTIAL SUMMARY JUDGMENT

Introduction

This patent infringement action was filed more than nine years ago. At the outset, plaintiffs asserted infringement of numerous claims under four patents relating to implantable cardiac defibrillators. A trial in 2001 on claims for infringement of four claims of two patents resulted in a verdict awarding plaintiffs $140 million in royalties for infringement of two claims of one patent, United States Patent No.

4,316,472. Following trial, this court resolved various post-trial motions and entered judgment for defendants on all claims. Both sides appealed to the United States Court of Appeals for the Federal Circuit. The Federal Circuit affirmed in part and remanded in part for reconsideration of the court's construction of the "determining" step limitation of Claim 4 of a different patent, United States Patent No. 4,407,288, and for a possible new trial of that one claim. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371 (Fed. Cir. 2004).

Claim 4 of the '288 patent is a method patent. A trial on that one remaining claim is scheduled for later this year. The parties have submitted proposed claim constructions for the disputed "determining" step limitation of Claim 4. Defendants have also asked the court to reinterpret the other limitations of Claim 4 in light of the revised claim construction of the "determining" step. In addition, both sides have filed several motions for summary judgment, only some of which are resolved by this Entry. The motions addressed here seek to narrow the scope of any new trial in terms of the defenses that would be available to defendants and the damages that could be pursued by plaintiffs.

As explained below, the court intends to adopt plaintiffs' proposed claim construction of the "determining" step limitation of Claim 4 of the '288 patent, with one minor change. The court denies plaintiffs' motion for summary judgment on defendants' affirmative defenses and counterclaims. The court denies defendants' motion as to plaintiffs' claim for lost profits, and grants in part and denies in

part defendants' motion to limit damages to implantable cardiac defibrillators shown to have used the claimed method in the United States.

Background

I. *Factual History*

Plaintiffs in this case are Cardiac Pacemakers, Inc., Guidant Sales Corporation, Mirowski Family Ventures, LLC, and Anna Mirowski (collectively, "CPI"). Defendants are St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, "St. Jude").

CPI's sole remaining claim in this case alleges that St. Jude infringed its patent for a method used to evaluate and treat abnormal rhythms of a patient's heart. The relevant patent is United States Patent No. 4,407,288 ("the '288 patent"), which expired in December 2003, after the first trial in this case. In general, the '288 patent claims improvements enabling "multimode" operation by implantable cardiac defibrillators ("ICDs"). ICDs are small, powerful devices implanted under the skin of a heart patient. They can detect abnormal heart rhythms, including ventricular fibrillation, which renders a person unconscious in seconds and is fatal within a few minutes unless corrected. Upon detecting an abnormal heart rhythm, an ICD can administer different types of electrical shocks to restore a normal rhythm to the heart. The '288 patent addresses "multimode" operation, meaning that the device can respond to an arrhythmia first with one type of electrical therapy and then, if the first therapy is not successful, can proceed automatically to administer

other types or modes of electrical therapy until the heart resumes a normal rhythm. Modes of electrical therapy carried out by the ICDs may include cardiac pacing (low power) and automatic defibrillation (with very powerful shocks), as well as "cardioversion," an intermediate form of therapy discussed below. A more detailed discussion of the technology is available in the court's numerous prior written decisions, including the original Entry on Claim Construction Issues, 2000 WL 1765358 (S.D. Ind. Nov. 29, 2000) (Docket No. 365), and the Amended Entry on Post-Verdict Motions, 2002 WL 1801525 (S.D. Ind. July 5, 2002) (Docket No. 960).

The only remaining claim at issue here is Claim 4 of the '288 patent. Claim 4, including Claim 1 on which it depends, claims:

> 1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:
> (a) determining a condition of the heart from among a plurality of conditions of the heart;
> (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
> (c) executing said at least one mode of operation of said implantable heart stimulator

thereby to treat said determined heart condition.

4. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.

'288 patent, col. 21, *ll.* 9-32.

II. *Procedural History*

A. *Jury Trial*

An overview of this case's procedural history is essential to understand the current motions. In June 2001, a jury heard CPI's claims for patent infringement against St. Jude on two claims in the '472 patent and two in the '288 patent. The jury rendered a mixed verdict. It found that St. Jude had infringed the '472 patent, and it rejected St. Jude's defenses that the '472 patent was invalid for failure to comply with the written description requirement of 35 U.S.C. § 112 ¶ 1, for obviousness, and for obviousness-type double patenting. The jury also found that St. Jude's infringement was not willful.

With regard to the '288 patent, the jury found that St. Jude had not infringed. The jury also rejected St. Jude's defenses that the '288 patent was invalid for failure to comply with the best mode requirement of 35 U.S.C. § 112 ¶ 1 and for obviousness, and that the '288 patent should be unenforceable because of CPI's allegedly inequitable conduct.

The jury found that CPI had not proved any lost profits, but the jury awarded royalties for infringement of the '472 patent in the amount of $140 million.

B. *Post-Verdict Motions*

Following trial, the court resolved numerous post-verdict motions that essentially decided for St. Jude on both patents and conditionally granted a new trial on several issues on which it did not prevail at trial. With respect to the '472 patent, the court granted St. Jude's motion for judgment as a matter of law, finding that neither one of the two claims of the '472 patent had been infringed. The court granted a conditional new trial on that issue with respect to Claim 18, but not for Claim 1. The court also addressed several of St. Jude's defenses relating to the '472 patent. First, the court found that the two claims of the '472 patent were invalid for failure to satisfy the written description requirement and granted St. Jude's JMOL motion and, alternatively, granted a conditional new trial on this defense. The court also found the two claims of the '472 patent invalid for obviousness-type double patenting, and granted St. Jude's JMOL motion, but denied its alternative request for a new trial. Finally, the court denied both St. Jude's JMOL motion and its alternative motion for a new trial on its obviousness defense to the two claims of the '472 patent.

With regard to the '288 patent, CPI requested a new trial on infringement, alleging that it had been denied a fair trial because of St. Jude's opening statement and its presentation to the jury to discuss

the inconsistent reports of one of CPI's experts. By way of background, the court and St. Jude learned during the trial that CPI's primary expert, Dr. Joseph Bourland, gave incorrect testimony in his pre-trial deposition and on the witness stand about his involvement in another pending ICD patent infringement action. The court therefore permitted St. Jude to point out to the jury the inconsistencies between the reports Dr. Bourland had authored for each of the two cases. After trial, the court allowed St. Jude to conduct discovery on Dr. Bourland's actions and testimony. Dr. Bourland admitted after trial that he had not been just honestly mistaken, but had deliberately lied in his trial testimony. Finding that CPI had not been denied a fair trial on this (or any other) basis, the court denied CPI's request for a new trial. The court also granted St. Jude's motion for sanctions and for a conditional new trial as a result of Dr. Bourland's conduct and CPI's related failure to comply with discovery obligations.

The court resolved other post-verdict issues related to the '288 patent. First, the court granted St. Jude's JMOL motion and alternative request for a new trial, finding that Claims 4 and 13 of the '288 patent were invalid for violating the best mode requirement of 35 U.S.C. § 112 ¶ 1. The court also granted St. Jude's JMOL motion and alternative request for a new trial, finding that Claims 4 and 13 of the '288 patent were invalid for obviousness. The court denied, however, St. Jude's JMOL motion and alternative request for a new trial on its defense that the '288 patent should be unenforceable because of CPI's inequitable conduct, relating to its failure to pay appropriate maintenance fees for the patent.

Finally, with respect to damages awarded for infringement of the '472 patent, the court granted St. Jude's motion for a conditional new trial on the issue of royalties, and denied CPI's contingent motion for a new trial on the issue of lost profits. This court entered an amended final judgment on July 5, 2002.[1]

C. *Federal Circuit Review*

CPI did not try to revive the $140 million verdict under the '472 patent, but it appealed the judgment as to the '288 patent. St. Jude cross-appealed on certain issues. The Federal Circuit reversed the court's grant of JMOL on the '288 patent and reinstated the jury verdict that the patent was not invalid for obviousness or for failure to satisfy the best mode requirement. See 381 F.3d at 1378, 1379. The Federal Circuit also reversed the court's conditional grant of a new trial on these issues. *Id.* at 1380.

CPI appealed the finding of non-infringement as to only Claim 4 of the '288 patent. The Federal Circuit held that this court had erred by construing the "determining" step element of Claim 4 as a "step-plus-function" limitation under 35 U.S.C. § 112 ¶ 6. The Federal Circuit did not, however, actually determine the proper construction of Claim 4. Nor did it grant CPI's request to find infringement as a matter of law. Instead, the Federal Circuit ordered this court to re-construe the "determining" step "in light of the specification and the prosecution history."

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[1] The court also denied St. Jude's JMOL motion on whether any lump sum initial royalty payment would be proper and did not reach CPI's motion for an award of prejudgment interest.

381 F.3d at 1382. The Federal Circuit concluded that a new trial of infringement was required because of the need for a new claim construction. *Id.* at 1383.

Next, the Federal Circuit vacated the court's conditional sanction that CPI would pay St. Jude's attorneys fees if a new trial for infringement was required. The court reasoned that the new trial ordered in this case would not have resulted from Dr. Bourland's deception and CPI's complicity in it. See *id.* at 1383.

Finally, the Federal Circuit considered CPI's request that the jury's $140 million damage award on the '472 patent simply be shifted by the court to the '288 patent. The court did not shift the damage award, stating that "damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand." *Id.* at 1383. The Federal Circuit summarized its rulings on the '288 patent as follows:

> We affirm in part and modify in part the district court's claim construction, reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages. We affirm the district court's decision upholding the patent term extension.

381 F.3d at 1374.[2]

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[2] Though not raised as issues here, St. Jude cross-appealed a previous ruling by this court that the '288 patent's term was properly extended and had not expired. The Federal Circuit affirmed this ruling.

The case is now before the court for claim construction and to resolve several motions for partial summary judgment.

Discussion

I. *Claim Construction of the '288 Patent*

A. *Standards for Claim Construction*

The court must construe ambiguous terms in a patent as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), the Federal Circuit restated the principles to be applied in claim construction. *Phillips* reaffirmed the importance of intrinsic evidence, *i.e.*, the claim language, specification, and prosecution history of a patent, for claim construction.

In considering the claim language, words are generally to be given their ordinary and customary meanings. *Phillips*, 415 F.3d at 1312. That is, the words of a claim are to be construed to have the meanings they would have for "a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. The starting point for applying this standard is understanding that "patents are addressed to and intended to be read by others of skill in the pertinent art," and not the public generally, or lawyers and judges. *Id.*

A patent's specification is highly relevant to the claim construction analysis. "Usually, it is dispositive; it is the single best guide to the meaning

of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), quoted in *Phillips*, 415 F.3d at 1315. The court also may consider the patent's prosecution history, which consists of the complete record of proceedings before the Patent and Trademark Office ("PTO") and the prior art cited during the patent's examination. Like the specification, the prosecution history provides evidence of how the PTO and inventor understood the patent. However, it often lacks the same clarity and is "less useful" than the specification for claim construction. *Phillips*, 415 F.3d at 1317. Nevertheless, the prosecution history can sometimes demonstrate whether the inventor limited the invention in the course of prosecution, thereby narrowing the scope of a claim. *Id.*, citing *Vitronics*, 90 F.3d at 1582-83.

Phillips also pointed out that extrinsic evidence (such as expert testimony, dictionaries, and learned treatises) is generally less helpful than intrinsic evidence and is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." 415 F.3d at 1319. The Federal Circuit acknowledged, however, that one proper use for extrinsic evidence can be to avoid the danger of reading limitations from the specification into the claim. *Id.* at 1323. *Phillips* reaffirmed the critical distinction between using the specification to interpret the meaning of a claim and improperly importing limitations from the specification into the claim. *Id.* With these standards in mind, the court addresses the proper construction of Claim 4.

B. *'288 Claim 1 and 4: "determining a condition of the heart from among a plurality of conditions of the heart"*

Claim 1 is incorporated by reference into Claim 4 of the '288 patent. Before the first trial, the court construed the "determining" step as a step-plus-function element that was illuminated by the patent's specification. The specification described the use of a combination of circuitry that measured the heart's rate and that used a technique known as probability density function, or "PDF." Using the step-plus-function approach, the court held before the first trial that the "determining" step was limited to methods using PDF as part of the process. The use of the step-plus-function approach was the reversible error at the heart of the Federal Circuit's remand.

Without using the mistaken step-plus-function mode of interpretation, the "determining" step is straightforward. The court intends to define "determining a condition of the heart from among a plurality of conditions of the heart" from Claim 1 for the jury as follows:

> Detecting which one of a number of heart arrhythmias exists, *i.e.*, whether there exists, *e.g.*, tachycardia, fibrillation, or bradycardia, or whether there exists a normal sinus rhythm. This step of "determining" may merely analyze heart rate to determine the condition of the heart.

This construction very nearly reflects the claim construction proposed by CPI.[3]

CPI's proposed construction is well-supported by the claim language. The "determining" step is the first step of a method for treating arrhythmias, rhythm disorders that typically result from problems with the heart's electrical system. The claim preamble calls for a device "capable of detecting a plurality of arrhythmias." The "determining" step is the only step in the claim that could address that basic requirement for the ICD. The "determining" step itself is not novel – it merely represents the initial step where one learns whether anything is wrong with the heart's rhythm, and if so what the problem is.

St. Jude argues that CPI's construction equates "determining a condition of the heart" with "detecting an arrhythmia," and that this is contrary to the claim language, specification, and prosecution history of the '288 patent. St. Jude argues that a "condition," as opposed to an "arrhythmia," can be determined only by logically analyzing both rate and PDF inputs.

St. Jude's proposed construction tries to complicate a simple element of the claim. Although the use of different claim terms can create a presumption of different meanings, see *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000), this principle does not dictate the outcome here. The

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[3] The heart's condition should usually be determined as "normal," so the court has revised CPI's proposed construction to account for this happy circumstance.

ordinary meaning of an "arrhythmia" is an irregular heartbeat. Remand Docket No. 107, CPI Ex. 13 at 7 (Dr. Berger's report: to one of ordinary skill in the art, "the only difference between an arrhythmia and a condition of the heart is that the term 'condition of the heart' would include a normal condition"). At the time of invention, several methods for detecting arrhthymias were well-known, and prior art had disclosed the use of rate circuitry alone. See Remand Docket No. 107, CPI Ex. 13 at 8-10 (Dr. Berger's report); Remand Docket No. 120, CPI Ex. 15 at 51-55 (Dr. Mihran's testimony that rate detector circuitry can detect conditions of bradycardia, tachycardia, and fibrillation).

The specification also supports CPI's proposed construction. The specification repeatedly refers to an "arrythmia" as a "heart disorder." See '288 patent, col. 1, *ll.* 23-28, 38, 53-54, 62-63; col. 4, *ll.* 8-10; col. 7, *ll.* 23-33 (describing object of invention to provide device and method capable of electrical heart stimulation "in response to detection of the occurrence of various heart disorders or arrhythmias"). Most important, CPI's proposed construction avoids, and St. Jude's invites, "one of the cardinal sins of patent law" – reading specific limitations in a specification's disclosed embodiment into the broader claim. See *Phillips*, 415 F.3d at 1320, 1323. The '288 specification discloses an embodiment that uses both rate and PDF detection circuitry to determine a heart's condition. See '288 patent, col. 9, *l.* 59 – col. 10, *l.* 28. However, apart from the rejected stepplus-function mode of interpretation, there is no indication that this disclosed embodiment was meant to exclude or disclaim devices that use rate circuitry

alone. As CPI points out, no particular circuitry is discussed in the patent's abstract, background of the invention, summary of the invention, or objects of the invention.

This case is readily distinguishable from both *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001), and *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999), where the court held that the patentees intended to claim only the preferred embodiments disclosed in their respective specifications. In *SciMed*, the patent specification criticized a dual lumen structure for catheters and stated that a coaxial lumen structure, the only alternative, was "the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." 242 F.3d at 1339. Based on this language in the specification, the Federal Circuit held that SciMed had disclaimed dual lumen catheters. *Id.* at 1343-44. Similarly, in *Wang Laboratories*, the court held that only the specified protocol was claimed, since the specification would not be understood by a person skilled in the field of the invention as including the other possible embodiment. 197 F.3d at 1382. Although the parties in *Wang Laboratories* agreed that the term "frame" could theoretically apply to either character-based or bit-mapped display systems, the specification's consistent illustration of "frame" using character-based protocol and the patent's prosecution history indicated that the claim referred only to character-based systems. *Id.* at 1382-84.

In this case, the '288 patent's claim language, specification, and prosecution history do not disclaim detection methods that are not "rate plus PDF." See, *e.g.*, '288 patent, col. 10, *ll.* 19-23 (stating that "conventional logic circuitry can be provided for determining, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia"). Absent specific reasons dictating a narrow claim construction, a particular embodiment in a specification will not limit broader claim language. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 907 (Fed. Cir. 2004).

St. Jude also contends that CPI's proposed construction of Claim 4 would render it invalid, and St. Jude points out that a claim ordinarily should not be construed in a manner that would render it invalid. See *Phillips*, 415 F.3d at 1327; *Carman Indus., Inc. v. Wahl*, 724 F.2d 932 (Fed. Cir. 1983). St. Jude argues that CPI's construction places no limit on how a heart condition is determined and therefore poses a host of invalidity problems, such as indefiniteness, failure to meet written description requirements, failure to enable, and anticipation. St. Jude argues that acceptance of CPI's construction for the "determining" step would allow non-ICD devices such as pressure monitors, stethoscopes, and oxygen monitors to fall within the claim.

The claim language and specification strongly support CPI's broader construction of the "determining" step element of Claim 4. Moreover, it is not clear at this point that CPI's construction will

lead to invalidity of the claim. The preference for claim constructions supporting validity is essentially a last resort, to be used only when the other tools for interpreting ambiguous claims have been exhausted. See *Phillips*, 415 F.3d at 1327-28 (noting that the doctrine of construing claims to preserve their validity is of "limited utility" and applies only when claim is ambiguous after applying all other tools of claim construction); see also *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356 (Fed. Cir. 1999) (doctrine not applicable where claim is reasonably susceptible of only one meaning). The consequences of the court's adopted construction are best addressed in the context of St. Jude's pending motion for summary judgment of invalidity or at trial.

C. *Remaining Limitations*

St. Jude contends that the new construction of the "determining" step directly affects other elements of Claim 4, requiring the court to revisit the interpretations of those elements as well. See Remand Docket No. 92, St. Jude Ex. H at 7 (Dr. Mihran's report). St. Jude also asks the court to interpret phrases from the preamble of Claim 1.

The Federal Circuit did not address whether other claim elements should be construed on remand. Its statement that "the 'determining' step must be construed, *as for all claim steps*, in light of the specification and the prosecution history" does not require that the court revisit the other elements in Claim 4. See 381 F.3d at 1382 (emphasis added). The statement merely highlights the appellate court's

recognition that its instructions for construing the "determining" step on remand in this case fit with its generally applicable standards for claim construction.

While the district court may not grant relief beyond the scope of the Federal Circuit's mandate, it may act on matters left open by the mandate. *Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed. Cir. 1997); see also *Exxon Corp. v. United States*, 931 F.2d 874, 877 (Fed. Cir. 1991) (law-of-the-case doctrine does not constrain the trial court with respect to issues it previously decided that were not also decided by the appellate court's judgment). It is doubtful that the Federal Circuit's single statement that it was affirming in part and modifying in part this court's claim construction, see 381 F.3d at 1374, meant that its judgment decided all claim construction issues, since these issues were not appealed by the parties nor discussed by the court. Also, this court's construction of Claim 4's other limitations could be subject to *de novo* review by the Federal Circuit if this case were to return to the appellate court. See *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*).

However, both parties fully briefed and argued these issues for the initial *Markman* hearing. St. Jude did not dispute this court's constructions either at trial or on appeal. Most important, St. Jude has not presented any convincing argument as to how the broader interpretation of the "determining" step affects the other claim elements. Because the court adopts CPI's proposed construction for the "determining" step, it is unnecessary to reconstrue "detecting an arrhythmia" to highlight the differences

between those two phrases. When asked in his deposition, St. Jude's own expert could not articulate what effect the broader interpretation of the "determining" step might have on the "cardioversion" limitation of the claim. See Remand Docket No. 120, CPI Ex. 15 at 104-05 (Dr. Mihran). Because St. Jude offers no persuasive reason for this court to reconstrue the other limitations, the court declines to do so.

To address several of the specific issues: First, "cardioversion," as it is used in "wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion" in Claim 4, is not limited to manual cardioversion. The patent specification clearly uses the term "cardioversion" generically to encompass both manual and automatic cardioversion. See, *e.g.*, '288 patent, col. 12, *ll.* 49-65 (using "cardioversion" in describing automatic operation of claimed device).

Second, St. Jude's argument for reinterpreting the "selecting" step is not persuasive. The "selecting" step states that operation of the implantable heart stimulator includes "a unique sequence of events corresponding to said determined condition." The court has previously construed the "unique sequence" language to involve "matching the currently determined heart condition to the unique set of instructions that have been programmed to treat the detected condition." See 2000 WL 1765358, at *35-36. St. Jude now asks the court to modify this instruction by adding that the device is incapable of "learning," *i.e.*, it will execute the same electrical stimulation

sequence each time a particular heart condition occurs.

This court previously found that the '288 patent did not claim a learning functionality. See 2000 WL 1765358, at *35 ("The court agrees with St. Jude's contention that the currently determined condition of the heart is the only variable that affects the step of 'selecting'"). However, the '288 patent's preferred embodiment does allow *physicians* to reprogram the ICD depending on the patient's reaction to treatment. See '288 patent, col. 5, *ll.* 27-45. Therefore, St. Jude's proposed construction, which requires that the same sequence of electrical stimulation occur *every* time a particular condition occurs, would not cover the '288 patent's preferred embodiment. Such an interpretation is unlikely to be correct. *Vitronics*, 90 F.3d at 1583.

Third, St. Jude's proposed changes to the court's construction of the "executing" step are minimal and unnecessary. The court addresses St. Jude's argument concerning infringement and the execution of all claimed method steps in Part IV of this Entry.

In sum, the court sees no need to revisit the elements of Claims 1 and 4 other than the "determining" step, and intends to use the constructions from its previous Entry on Claim Construction Issues (Docket No. 365).

II. *CPI's Motion for Summary Judgment on St. Jude's Second, Fourth, Fifth, Sixth, and Seventh Affirmative Defenses and Related Counterclaims*

CPI has moved for summary judgment on St. Jude's invalidity and unenforceability defenses and related counterclaims. CPI contends the Federal Circuit rejected those defenses conclusively. The motion is denied. The Federal Circuit's remand left open the possibility of new invalidity and unenforceability defenses. The Federal Circuit wrote: "We . . . reinstate the jury verdict of validity, and remand for a new trial of infringement and reassessment of damages." 381 F.3d at 1374. The court also wrote that a "new trial is required so [St. Jude] can present evidence and argument that were not needed under the district court's original claim construction, such as whether the now-asserted scope of the claims is supported by the specification." *Id.* at 1382-83. That language plainly leaves open the possibility of affirmative defenses.

A. *Invalidity*

St. Jude has asserted as affirmative defenses that the '288 patent is invalid and unenforceable. See Remand Docket No. 40 at 3, ¶ 2. CPI points out that the jury previously found against St. Jude on the issues of obviousness and best mode for the '288 patent. Although this court granted JMOL and a conditional new trial to St. Jude on these issues, the Federal Circuit reinstated the jury's findings that (1) the '288 patent was not invalid for obviousness under 35 U.S.C. § 103 and (2) the '288 patent had not

violated the best mode requirement in 35 U.S.C. § 112. 381 F.3d at 1378, 1379. The Federal Circuit also vacated this court's conditional grant of a new trial on these issues. *Id.* at 1380.

CPI argues that a different construction of the "determining" step does not affect either obviousness or the best mode issue. With respect to obviousness, CPI concedes that the "determining" step limitation, however it is construed, was present in prior art. CPI Br. at 5. CPI argues that the parties' obviousness debate focused on other features in the claimed invention (*e.g.*, multimode operation), and that these features are not affected by the court's new construction. With respect to best mode, this court had held the '288 patent invalid for failure to disclose use of the Honeywell battery. CPI contends that St. Jude never made a best mode argument relating to Claim 4's "determining" step. Based on the failure of these defenses before the Federal Circuit, CPI argues that St. Jude should be foreclosed from raising any invalidity defenses on remand.

The Federal Circuit's decision does not generally bar St. Jude from asserting invalidity defenses and related counterclaims on remand. When a new trial on infringement is ordered, a defendant is generally entitled to present any defenses to infringement that may be available and that are not foreclosed by the appellate court's mandate. In this case, the Federal Circuit's mandate, including its reinstatement of the jury's verdict on obviousness and best mode, did not foreclose all of St. Jude's validity defenses under a new claim construction in a new trial for infringement. Of course, the mandate rule precludes

St. Jude from asserting the same obviousness and best mode arguments it raised and lost earlier in the litigation. See *Ins. Group Committee v. Denver & R.G.W.R. Co.*, 329 U.S. 607, 612 (1947) (mandate rule requires that a lower court "refuse to permit the relitigation of matters or issues previously determined on a former review"). However, St. Jude's other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand. See *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 137 F.3d 1475, 1478 (Fed. Cir. 1998) ("Even without the express disclaimer in the court's opinion, it would be incorrect to conclude that the court's mandate encompassed an issue that was not presented to the court.").

Three points support this conclusion. First, the Federal Circuit suggested that a new claim construction might give rise to new invalidity defenses when it noted that St. Jude could present evidence and argument on remand, "such as whether the now-asserted scope of the claims is supported by the specification." 381 F.3d at 1382-83. Clearly implicit in this language is the invalidity defense based on the written description requirement of 35 U.S.C. § 112.

Second, St. Jude had no obligation on appeal to present alternative arguments for invalidity since it had succeeded on its obviousness and best mode points in this court. See *Lubrizol*, 137 F.3d at 1482 (vacating district court's denial of new trial on infringement under doctrine of equivalents; patentee could not be held to have abandoned theory that was moot until appellate court reversed jury verdict on

literal infringement; finding of waiver "would require an appellee to anticipate every possible claim construction that the appellate court might adopt and put forth grounds for a new trial under each possible claim construction"); *Laitram*, 115 F.3d at 951-55 (issues made moot by district court's resolution of separate issue later reversed on appeal were not foreclosed on remand either by mandate rule or doctrine of waiver); *Cordis Corp. v. Medtronic Ave, Inc.*, 2005 WL 283525, at *2 (D. Del. Jan. 27, 2005) (invalidity defense that theoretically could have been asserted at trial but might have resulted in jury confusion was not waived under new claim construction). Even if St. Jude could have made invalidity arguments contingent on the success of CPI's appeal on the claim construction, it was not required to do so. If the law were otherwise, complex appeals in cases like this would become even more complex and difficult to manage.

Most important, because of the court's previous claim construction, St. Jude may have chosen not to pursue some invalidity defenses, including anticipation, at trial. But because anticipation requires specific reference to all claim elements, it is possible, for example, that the court's previously adopted claim construction steered St. Jude away from other art that would be relevant to this defense under a revised claim construction. It is also possible that the first trial's primary focus on apparatus claims, as opposed to the lone method claim that now remains, led St. Jude to focus on different invalidity defenses than it might assert now. See, *e.g.*, *TI Group Automotive Systems (North America), Inc. v. VDO North America, LLC*, 375 F.3d 1126, 1139 (Fed Cir.

2004) (remanding invalidity question because "jury could only have compared the prior art to the erroneously narrowly construed claims"); *Cordis Corp.*, 2005 WL 283525, at *2 (denying plaintiff's motion for summary judgment that defendants had waived obviousness argument on remand; issue had changed as a result of revised claim construction). St. Jude did not abandon or waive invalidity defenses that became relevant only on remand, where the court's new claim construction is broader than the original. Cf. *Cordis*, 2005 WL 283525, at *2 ("it is unrealistic to have expected Medtronic to present invalidity arguments in the original trial if it thought such arguments were futile based on the narrower claim construction at issue"). St. Jude's motions for summary judgment of invalidity of Claims 1 and 4 (Remand Docket Nos. 80 & 81) raise more than a mere theoretical possibility that different invalidity defenses are now available.

B. *Unenforceability*

CPI also seeks to exclude St. Jude's defenses and counterclaims relating to CPI's alleged misconduct before the Patent and Trademark Office and during the first trial. St. Jude argues that the '288 patent is unenforceable on the grounds of unclean hands, estoppel, inequitable conduct, and fraud. The court holds that *all* of St. Jude's arguments concerning unenforceability may be asserted on remand as well.

St. Jude's unenforceability arguments on remand fall into three broad categories. First, St. Jude alleges that CPI engaged in several types of misconduct before the PTO. At trial, St. Jude alleged

that CPI made misrepresentations to the PTO in 1994 to secure extension of its '288 patent and in 1998 by claiming that its failure to pay correct maintenance fees was a filing error. The jury rejected St. Jude's inequitable conduct defense on these issues, and the court denied St. Jude's motion for JMOL. Also, prior to trial, St. Jude alleged that CPI had engaged in inequitable conduct by failing to disclose material information to the PTO during the original prosecution and reexamination of the '288 patent, but it did not pursue either theory at trial. St. Jude also had alleged that CPI misrepresented another patent during reexamination of the '288 patent, but it did not pursue that theory at trial. On remand, St. Jude seeks to revive each of these arguments. See Remand Docket No. 40 at 8-9, ¶¶ 18-23; at 4, ¶¶ 6-7; at 6-7, ¶ 14; and at 7, ¶ 17.

Second, St. Jude previously alleged that CPI had asserted three patents against St. Jude that it knew were invalid. The court granted summary judgment for CPI on St. Jude's counterclaim. Docket No. 559. St. Jude did not appeal the order. St. Jude raises this issue again on remand. See Remand Docket No. 40 at 9, ¶ 24.

Third, St. Jude seeks to introduce evidence concerning Dr. Bourland's misconduct at the first trial. See Remand Docket No. 40 at 10, ¶ 25 to 15, ¶ 44. At the end of the first trial, the full extent of Dr. Bourland's misconduct and CPI's involvement was not known. In the post-verdict entry, this court stated that "if any claim by CPI that was tried to the jury survives an appeal, Dr. Bourland's deception entitles St. Jude to a new trial." 2002 WL 1801525, at *64.

The court also ordered a conditional sanction requiring CPI to pay St. Jude's attorneys fees on retrial. *Id.* at *64-65.

On appeal, the Federal Circuit vacated the court's conditional sanction because the new trial it ordered as a result of the erroneous claim construction was "unrelated to the witness' deception." 381 F.3d at 1383. The Federal Circuit did not address this court's findings concerning Dr. Bourland's conduct or St. Jude's inequitable conduct defense.

The Federal Circuit's mandate only vacated the court's conditional sanction of attorneys fees against CPI. The opinion and mandate did not even suggest, let alone require, that the issue of Dr. Bourland's misconduct be removed from this case for all purposes. See *Laitram*, 115 F.3d at 951 (appellate court's mandate extends only to matters decided explicitly or by necessary implication). This court's entry clearly stated that Dr. Bourland's conduct could be litigated in a new trial. CPI and the Federal Circuit did not address this ruling on appeal. The court's opinion emphasized that the information known at the end of trial might not have been a complete account of Dr. Bourland's misconduct or CPI's and its attorneys' involvement, and that it might not have fully accounted for the ways in which CPI's misconduct had affected St. Jude's success at trial. The court concluded that, if its reasons for finding against CPI on its infringement claims were rejected on appeal, the remedy should be "tailored more closely to the harm caused, which would be the need for a new trial." 2002 WL 1801525, at *63.

Accordingly, St. Jude is entitled to raise the issue of Dr. Bourland's misconduct at a new trial, whether asserted as inequitable conduct or some other legal theory.

In addition, the court believes that St. Jude is entitled to put in evidence relevant to CPI's *entire pattern* of allegedly inequitable conduct. As a question of law, a defense of inequitable conduct requires consideration of the totality of the circumstances, both those that support the defense and those that weigh against it. See, *e.g.*, *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1259 (Fed. Cir. 1997) (finding inequitable conduct as a matter of law based on pattern of conduct); *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 910 F.2d 804, 809 (Fed. Cir. 1990) (affirming finding of inequitable conduct based on totality of circumstances); *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989) (stating that inference of intent to mislead PTO "depends upon the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith").

Second, new post-trial information on CPI's conduct sheds additional light on CPI's efforts to enforce the patents in suit. For example, CPI's counsel told the jury that Dr. Bourland's false testimony was the product of an honest but mistaken memory. It is now clear that Dr. Bourland lied deliberately, and that CPI's trial attorneys made no reasonable effort to address the problem when it arose during trial. There is an interesting parallel

with the evidence of the fee issue that was the basis of the inequitable conduct defense at trial: CPI explained away its actions as honest mistakes, though there was certainly some additional circumstantial evidence that would have permitted, though not required, a finding of deliberate deception. A trier of fact who was aware of both patterns of activity, as well as such matters as the double-patenting in the '472 patent and other topics, might be less willing to give CPI the benefit of the doubt on the explanation that it had simply made honest mistakes.

After the first trial, this court stated: "in the event of a new trial on the '288 patent, based on Dr. Bourland's conduct, discussed next, *or for other reasons*, the inequitable conduct defense shall be part of the trial." 2002 WL 1801525, at *48 (emphasis added). St. Jude is entitled to raise its allegations of inequitable conduct, fraud, or unclean hands in a second trial. CPI's motion for summary judgment on St. Jude's affirmative defenses and related counterclaims is denied in all respects.

III. *St. Jude's Motion for Summary Judgment on CPI's Claim for Lost Profits*

A. *Waiver*

St. Jude first argues that CPI has waived its lost profits claim on the '288 patent because it chose not to appeal either the jury verdict or this court's denial of a new trial for lost profits on the '472 patent. Because lost profits are merely a function of how many infringing products are sold, CPI's expert

acknowledged that the measure of lost profits would not differ depending on which patent is found infringed. See Remand Docket No. 84, St. Jude Ex. 6 at 1175-76 (Britven's testimony). Nonetheless, CPI argues that it was not required to challenge lost profits for the '288 patent on appeal because the jury did not find infringement on that patent.

The doctrine of waiver prevents a party from raising an issue on remand that it should have raised previously on appeal. See, *e.g.*, *Tronzo v. Biomet, Inc.*, 236 F.3d 1342, 1347-48 (Fed. Cir. 2001). In this case, the jury did not find infringement of the '288 patent. It never reached the issue of damages under that patent. In addition, this court's order denying CPI's contingent motion for a new trial on lost profits related only to the '472 patent because the motion depended on a reviewing court finding that the '472 patent was not invalid. See 2002 WL 1801525, at *76-77. Accordingly, for purposes of deciding waiver, the lost profits issue, as it applies to the '288 patent, cannot be considered within the scope of the judgment that was appealed. Cf. *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1382 (Fed. Cir. 1999) ("The scope of the issues presented to this court on appeal must be measured by the scope of the judgment appealed from, not by the arguments advanced by the appellant.") (internal citations omitted). Argument on lost profits for the '288 patent was unnecessary, and indeed hypothetical, until the Federal Circuit reversed the court's construction of Claim 4 and remanded for a new trial on infringement. See *Laitram*, 115 F.3d at 954 (no waiver on remand for failure to appeal issue that was

moot until appellate court reversed judgment on appeal).

This analysis is not changed even though there may be no practical difference in the measure of lost profits between the '472 and the '288 patents. The Federal Circuit's actions and words caution this court to treat the two patents independently, at least with respect to damages. On appeal, the Federal Circuit refused to shift CPI's damages award from the '472 patent to the '288 patent, stating only that "damages for infringement of the '288 patent, should infringement be found on remand, requires determination on remand." 381 F.3d at 1383. Although St. Jude argues that this decision can be explained by the fact that royalty damages depend in part on the value of the particular patent that has been found infringed, the court hesitates to read this unstated rationale into the Federal Circuit's decision so as to prevent a party from litigating an issue that the jury did not decide directly before. If a new trial results in a finding of infringement of the '288 patent, a new determination of damages must occur.

This case is distinguishable from *Tronzo v. Biomet, Inc.*, which St. Jude cites as an example of waiver in the district court following an appeal. 236 F.3d 1342 (Fed. Cir. 2001). In *Tronzo*, a jury found defendant Biomet liable for patent infringement and other state law claims, and it awarded both compensatory and punitive damages. The trial court entered a judgment for $7.1 million in compensatory damages and $20 million in punitive damages. It also denied Biomet's post-trial motion to set aside the jury award of punitive damages. On appeal, Biomet

challenged its liability and the amount of compensatory damages, but it did not challenge the punitive damages award. The Federal Circuit reversed the finding of infringement, upheld liability on the state law claims, and remanded for a new determination of compensatory damages.

On remand, the district court reduced both the compensatory and punitive damages awards. The patent holder then appealed, arguing that Biomet had waived its right to challenge the punitive damages award by not appealing the award the first time around. The Federal Circuit agreed and reinstated the original $20 million punitive damages judgment.

The outcome in *Tronzo* depended on the fact that the punitive damages award was within the scope of the initial judgment. Biomet had an opportunity to challenge it in the first appeal, and it waived its opportunity to do so when it did not use that opportunity. See *id.* at 1348-49 (noting that district court had considered the issue below). In this case, neither the jury nor the court made any finding on lost profits for the '288 patent. The issue simply was not within the scope of the appealable judgment, and CPI was not required to raise it on appeal. Cf. *Engel Industries*, 166 F.3d at 1383 (no argument permitted on remand for issue within scope of judgment appealed from where appellate court did not order remand on any issues). Accordingly, this court cannot conclude that CPI has waived its claim to lost profits on the '288 patent.

B. *Merits*

Alternatively, St. Jude asks the court to find that CPI's claim for lost profits fails as a matter of law because CPI cannot establish that it lost any sales it would have made but for St. Jude's alleged infringement. A patentee claiming lost profits must prove that but for the infringement, it would have made a portion of the defendant's sales and made profits on those sales. *Grain Processing Corp. v. American Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). The relevant facts here are unusual. The alleged infringement occurred in this case when St. Jude acquired Ventritex, an existing market competitor. Ventritex had a license to practice the '288 patent. The license expired with the change of corporate control. St. Jude had made arrangements with another business to acquire a comparable license in a separate but simultaneous transaction. An arbitrator eventually ruled that the separate transaction did not provide St. Jude with a valid license, thus exposing it to claims for infringement. See *Telectronics Pacing Systems, Inc. v. Guidant Corp.*, 143 F.3d 428 (8th Cir. 1998) (compelling arbitration); *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 149 F. Supp. 2d 610 (S.D. Ind. 2001) (finding that arbitrator's ruling was binding on parties to this lawsuit).

St. Jude argues that in the hypothetical "but for" market, St. Jude would not have closed its merger with Ventritex, and therefore Ventritex's ICDs would have remained on the market as a non-infringing alternative to CPI's products. St. Jude claims that it is undisputed that Ventritex had an established

market share and a license to the '288 patent. Remand Docket No. 84, St. Jude Ex. 6 at 1230, 1241 (Britven's testimony). St. Jude also claims that CPI's own market share actually increased following St. Jude's merger with Ventritex. *Id.* at 1228. Based on this evidence, St. Jude argues that CPI cannot prove any lost profits as a matter of law.

Genuine issues of material fact prevent the court from finding that CPI's claim for lost profits should fail as a matter of law. The court could grant St. Jude's motion for summary judgment only if no reasonable jury could find in favor of CPI, the non-moving party, based on the evidence in the record. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986); *American Airlines, Inc. v. United States*, 204 F.3d 1103, 1108 (Fed. Cir. 2000). At the first trial, CPI failed on its claim for lost profits under the (invalid) '472 patent. However, CPI presented evidence from which a reasonable jury could have concluded that it suffered lost profits on sales of ICDs following St. Jude's merger with Ventritex, despite Ventitrex's pre-merger license to its patents.

On remand, CPI again can come forward with evidence to support a prima facie case for lost profits under the *Panduit* test. See *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978); *Micro Chemical, Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003) (recognizing *Panduit* test as one way to demonstrate entitlement to lost profits "but for" infringement); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991) (approving jury instruction on *Panduit* test in case for infringement of only method claims). Under

the *Panduit* test, a patentee must show: (1) demand for the patented product; (2) the absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit it would have made. *Panduit Corp.*, 575 F.2d at 1156. In a multi-supplier market, the patentee may substitute proof of market share for the second factor. *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989).

CPI has presented evidence of demand for its patented products. CPI can present evidence of market share, and an increase in CPI's market share during the alleged infringement period is not necessarily inconsistent with lost profits if the overall market was expanding. For the third *Panduit* factor, CPI has presented evidence of its capacity to manufacture additional ICDs. Finally, CPI can offer evidence on the amount of lost profits through expert testimony as in the first trial.

The court intends to provide essentially the same jury instructions on lost profits that it gave at the first trial. After setting forth the *Panduit* test, the court explained in part:

> As you know, Ventritex was licensed to practice the '472 and '288 patents before it merged with St. Jude and Pacesetter. Because the merger caused the termination of that license, any infringement began with the merger. If that merger had not occurred (that is, if the infringement had not occurred), the license would have allowed Ventritex to continue manufacturing and selling its

> products as an independent company. When reconstructing the market in the absence of the infringement, you may take this possibility into account.

Remand Docket No. 84, St. Jude Ex. 3 at 122 (Court's Final Instruction No. 60).

CPI argues, as it did at trial, that the court's instruction misstated the law. CPI contends that the Federal Circuit's decision in *Grain Processing* and its progeny permit a fact-finder to consider only alternative products that were available to the alleged infringer. CPI argues that the jury may not consider more broadly the alternative actions that the alleged infringer might have taken had it not infringed. In the context of this case, CPI claims that it was improper for the jury to consider the possibility that St. Jude might not have merged with Ventritex, so that Ventitrex could have continued to sell ICDs with a license on CPI's patents.

CPI raised this same objection prior to the first trial and in its contingent motion for a new trial. The court declined to adopt CPI's interpretation of the law and denied its post-trial motion on this issue. CPI did not appeal that denial.

On remand, CPI argues that more recent case law demonstrates that *Grain Processing* cannot be read so broadly as to include alternative actions by alleged infringers, such as a decision by St. Jude not to merge with Ventritex. CPI cites the Federal Circuit's decision in *Micro Chemical, Inc. v. Lextron, Inc.*, 318 F.3d 1119 (Fed. Cir. 2003), and several

district court decisions. It argues that these cases show that the "but for" infringement inquiry must be narrower.

The cases cited by CPI do not require a change in this court's interpretation of *Grain Processing* or its application to this case. Recent cases have focused only on the speculation surrounding the substitute product itself, *i.e.*, whether the infringer could establish that the product was both available and acceptable in the market during the relevant accounting period. For example, *Micro Chemical* simply reaffirmed the *Grain Processing* conclusion that the mere possession of material goods and know-how for making a substitute product may not be sufficient for finding that the alleged infringer could have brought the product to the market. In *Micro Chemical*, the Federal Circuit held that the defendant's product could not be considered available as a substitute because it took over four months to be converted into a non-infringing form. 318 F.3d at 1123; see also *McGinley v. Franklin Sports, Inc.*, 192 F. Supp. 2d 1214, 1220-22 (D. Kan. 2002) (denying infringer's motion for summary judgment on lost profits where evidence conflicted as to market acceptability of substitute product); *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 166 F. Supp. 2d 1008, 1030 (D. Del. 2001) (denying JMOL to cap damages award against defendant where non-infringing substitute had not been "finalized, approved, or implemented" during relevant accounting period), *aff'd in part, vacated in part, remanded on other grounds*, 370 F.3d 1131 (Fed. Cir. 2004); *Bose Corp. v. JBL, Inc.*, 112 F. Supp. 2d 138, 160 (D. Mass. 2000) (finding record was "too scant on

the availability of 'acceptable' substitutes to be persuasive"); *Cordis Corp. v. Boston Scientific Corp.*, 2005 WL 1322953, at *2 (D. Del. June 3, 2005) (ability to make non-infringing substitute alone is insufficient to render product "available" for lost profits purposes).

CPI cannot dispute that Ventritex's ICD was identical to the accused product and available for market at the time of the alleged infringement. Moreover, the cases cited by CPI do not speak more generally to the debate over whether the hypothetical "but for" market can include other non-infringing actions by the defendant. *Grain Processing* instructs that the court's reconstruction of the market "take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed," without the restrictions CPI proposes. 185 F.3d at 1350-51. Applying this principle here, one non-infringing alternative available to St. Jude was a decision not to close on its merger with Ventritex, leaving Ventritex with a valid license to compete independently in the market.

Because there is a genuine factual dispute as to whether this available alternative meant that CPI suffered no lost profits, St. Jude's motion for summary judgment on CPI's claim for lost profits is denied.

IV. *St. Jude's Motion for Summary Judgment Limiting CPI's Damages*

A. *Waiver*

St. Jude seeks to limit CPI's damages claim to only those devices that actually executed CPI's claimed method of cardioversion in the United States during the relevant infringement period. As an initial matter, CPI argues that St. Jude has waived this argument by raising it for the first time on remand. The court finds no waiver of this issue.

CPI has now narrowed its claims against St. Jude to a single method claim. CPI originally asserted both a method claim (Claim 4) and an apparatus claim (Claim 13) under the '288 patent. On the apparatus claim, a finding of infringement would have made St. Jude liable for *all* device sales. The method claim did not add to the scope of the infringement claim based on the apparatus claim. St. Jude therefore had no strong incentive to try to limit its damages with respect to the method claim in particular. After this court upheld the jury's verdict of non-infringement of the '288 patent, CPI abandoned the apparatus claim when it chose not to appeal any findings on the apparatus claim. In other words, St. Jude had no reason to present its present damages argument until the remand. Under the reasoning of the cases cited above at pages 23-24, there was no waiver.

B. *Actual Use of Claimed Method*

St. Jude argues that CPI can prove infringement of Claim 4 of the '288 patent only by showing that St.

Jude's devices were actually programmed to execute the claimed method of cardioversion or that they actually executed cardioversion. St. Jude contends that the method claimed in Claim 4 was not practiced in a large number of its ICDs. The point is critical here because CPI, to avoid problems of obviousness, chose not to pursue claims of infringement of Claims 3 and 5. Claim 3 is for: "The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes a cardiac pacer mode of operation." Claim 5 is for: "The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes automatic defibrillation." Cardiac pacing and automatic defibrillation are the most common forms of therapy administered by ICDs.

St. Jude's ICDs must be programmed before they can deliver any therapy to the patient. See Remand Docket No. 84, St. Jude Exs. 8 & 9 (Shipman Decl. ¶ 4; Kadish Decl. ¶ 3). St. Jude has presented evidence that a number of its devices implanted during the relevant infringement period were programmed by implanting physicians to "DEFIB ONLY" mode, making them incapable of executing a separate "cardioversion" therapy unless and until they were reprogrammed. See Remand Docket No. 84, St. Jude Exs. 8 & 9 (Shipman Decl. ¶¶ 5-6; Kadish Decl. ¶ 4); Hearing Tr. at 118 (discussing availability of statistical data as to how St. Jude devices were programmed and used in clinical trials).

St. Jude cannot be held liable for infringement of Claim 4 on a device that was not programmed to execute the claimed method of cardioversion and/or

that has not executed the claimed method of cardioversion. This issue previously arose with respect to infringement of Claim 18 of the '472 patent. In the post-verdict entry, this court stated:

> To hold St. Jude liable for infringement on this method claim – whether for inducing infringement or contributory infringement or direct infringement – CPI was required to come forward with some evidence of actual use of the infringing method by someone. See *Met-Coil Systems Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement). A method claim is not infringed by the sale of a device that is merely capable of being used in an infringing manner. Actual infringing use must be shown. *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 773-75 (Fed. Cir. 1993) (reversing finding of infringement of method claims where no actual infringing use was shown); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991) (method claims held not directly infringed by the mere sale of an apparatus capable of performing the claimed process).

2002 WL1801525, at *29 (granting JMOL on non-infringement because of absence of evidence of actual infringing use). Recent cases reaffirm this requirement. See, *e.g.*, *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("well-established that a patent for a method or

process is not infringed unless all steps or stages of the claimed process are utilized"), quoting *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976); see also *Imagexpo, LLC v. Microsoft Corp.*, 284 F. Supp. 2d 365, 369-70 (E.D. Va. 2003) (holding that patent holder could recover on only those devices distributed by alleged infringer and employed by the end user to use the patented method). Absent proof that St. Jude's devices were programmed for and actually executed the claimed method, CPI may not recover damages for the sales of devices merely capable of infringing. See 35 U.S.C. § 284 (damages available for "use made of the invention by the infringer").

CPI emphasizes that all of St. Jude's devices were capable of executing cardioversion therapy, and CPI contends that St. Jude even instructed physicians how to program its devices to execute this therapy. See Remand Docket No. 84, St. Jude Exs. 9 (Ex. A) & 11 (Reiss Aff. ¶¶ 24-27). CPI also argues that devices incapable of multimode operation would not have been marketed or implanted after the mid-1990s because physicians wanted the flexibility to later reprogram for cardioversion therapy. Remand Docket No. 125, CPI Ex. 1 at 281 (Dr. Tacker's testimony) and 1068 (Verrastro's testimony); CPI Ex. 2 (Berger Aff. ¶¶ 5-9).

None of these facts are sufficient to impose liability (and therefore damages) for every device sold. The case law cited above draws a clear distinction between method and apparatus claims for purposes of infringement liability. An apparatus claim is infringed when a product containing the

patented invention is made, used, offered for sale, or sold in the United States. See 35 U.S.C. § 271(a). But a method claim, like CPI's remaining claim in this case, is not infringed unless the patented method is *actually practiced*. St. Jude cannot be held liable for infringement of the '288 patent unless its ICDs were used by others to practice each step of the patented method.[4]

This important distinction between apparatus claims and method claims explains why the cases cited by CPI are not persuasive here. CPI argues that a patentee may recover damages for all sales when the ability to practice the patented feature is fundamental to the product's value. For example, in *Stryker Corp. v. Intermedics Orthopedics, Inc.*, the Federal Circuit affirmed a damages award based on all of the defendant's sales even though the components comprising the patented invention were used together only about 20 percent of the time. 96 F.3d 1409 (Fed. Cir. 1996). Stryker's patent covered a femoral prosthesis device. The patent required that the prosthesis include a distal sleeve. The defendant sold over 20,000 "APR II" prostheses but fewer than 5,000 sleeves. The Federal Circuit permitted Stryker to recover damages for all 20,000 prostheses sold, concluding that it was the availability of distal sleeves that was important to physicians, regardless of whether they were ultimately used in surgery. The court reasoned that "by supplying the APR II to

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[4] St. Jude does not concede that CPI has proven all of the other elements for contributory infringement or inducement of infringement, see St. Jude Br. at 2 n.1, but the court need not resolve those issues here.

surgeons, [Intermedics] kept [Stryker] out of the operating room." *Id.* at 1417.

CPI argues that St. Jude similarly kept it out of the operating room by selling ICD devices that were capable of cardioversion, regardless of whether this mode was actually programmed or executed for a particular patient. CPI's argument overlooks the fundamental fact that *Stryker* involved an apparatus claim and not a method claim. The basis for the *Stryker* court's decision was its recognition that Stryker was damaged by the defendant "each time [Intermedics] supplied an APR II system, complete with a distal sleeve, to a surgeon." *Id.* at 1417. That is, the apparatus patent was directly infringed by each sale of the device, whether it was used or not. As explained above, however, the method of Claim 4 is infringed only when every step of the claimed method is executed. The reasoning of *Stryker* does not apply to CPI's remaining method claim. See also *Oak Indus., Inc. v. Zenith Electronics Corp.*, 726 F. Supp. 1525, 1543 (N.D. Ill. 1989) (granting summary judgment for defendant to limit plaintiff's damages to cable converters shown to have practiced the patented method, rather than all converters that were capable of performing the method).

CPI points to other cases holding that a product may be found to infringe when it sometimes, but not always, practices the claimed method. See *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995) (vacating summary judgment of non-infringement of patented method and cautioning that product only sometimes performing patented method

may nonetheless infringe); see also *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001) (vacating summary judgment of non-infringement but noting that operation of accused device under unusual conditions may not establish infringement). These cases are also inapposite. CPI's argument confuses the distinction between all devices sometimes practicing the patented method and the very different situation of some devices never practicing the patented method. St. Jude contends that its devices, similar to the cable converters in *Oak Industries*, fall into the latter category.

By abandoning its apparatus claim, CPI has radically altered the relevant considerations for potential damages. As a matter of law, CPI's damages for infringement of Claim 4 of the '288 patent are limited to only those devices that can be shown to have executed the claimed method of cardioversion during the relevant infringement period.

C. *Applicability of Section 271(f)*

St. Jude seeks another limit on CPI's available damages. St. Jude argues that CPI may recover damages only on devices it sold in the United States. Devices sold outside of the United States that do not practice the claimed method domestically cannot create infringement liability under 35 U.S.C. § 271(a). See *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005). However, CPI argues that it is entitled to recover damages for St. Jude's foreign sales under 35 U.S.C. § 271(f).

Section 271(f) was adopted in 1984 to close a loophole exposed by *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), that allowed parties to avoid infringement liability by manufacturing components of a patented product in the United States and then shipping those components abroad for assembly. Section 271(f)(1) reads:

> Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f)(1). CPI argues that this provision applies to St. Jude because St. Jude supplied its ICD "components" abroad, thereby actively inducing the combination of its devices with the steps of CPI's patented method to infringe Claim 4 of the '288 patent.[5]

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[5] CPI does not appear to suggest that St. Jude would be liable under 35 U.S.C. § 271(f)(2), which creates liability for entities supplying "any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use . . . knowing that such a component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination

CPI points to several recent decisions by the Federal Circuit that it argues demonstrate the applicability of section 271(f) to method claims. First, in *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005), the specific issue was whether software code developed in the United States, shipped abroad on master disks, and then downloaded onto computer hard drives for foreign sales constituted "components" of an infringing product for combination outside of the United States under section 271(f). The patentee had sued Microsoft for allegedly infringing its internet browsing software through domestic and foreign sales of Internet Explorer. The district court held that section 271(f) applied to the software code shipped abroad, and the Federal Circuit agreed. The Federal Circuit emphasized that "every component of every form of invention deserves the protection of section 271(f)." *Id.* at 1339.

In *AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366 (Fed. Cir. 2005), the Federal Circuit again confronted Microsoft, exported software code, and section 271(f). The court held that sending a master version of software abroad with the intent of replication fell within section 271(f) liability for foreign-made copies. 414 F.3d at 1370. While the court did not discuss section 271(f) in detail outside of the software context, it once again noted that the statute "should be construed broadly to effectuate its purposes." *Id.* at 1371, citing *Tcherepnin v. Knight*, 389 U.S. 332, 336 (1967).

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occurred within the United States." See CPI Br. at 6.

St. Jude correctly points out that the plaintiffs in *Eolas* and *AT&T Corp.* had asserted both product and method claims. St. Jude argues that because the product claims embodied the method claims in those cases, the court's discussion of section 271(f)'s application to method claims was mere dicta. St. Jude contends that the plain language and legislative history of section 271(f) show that the statute was intended only to prevent companies from avoiding liability by assembling components of a patented physical product outside of the United States. St. Jude also argues that use of the word "component" in reference to a method step would be inconsistent with the use of that term in other provisions of section 271, and that the notions of "combining" or "supply" make no sense in the context of method claims. Finally, St. Jude points out that if section 271(f) were applied as CPI suggests, St. Jude could be liable for more damages on its foreign sales of ICDs than on its domestic sales of the same devices.

St. Jude's arguments have considerable weight, especially in light of the statutory language: "in a manner that would infringe the patent if such combination occurred within the United States." The mere assembly of an ICD that is capable of infringing the method of Claim 4 simply does not infringe Claim 4 within the United States. Only infringing use of the method infringes the method claim.

Nevertheless, the Federal Circuit's even more recent decision in *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366 (Fed. Cir. 2005), seems to point in the opposite direction. In *Shell Oil*, the plaintiff's patent claimed a more

efficient process for producing ethylene oxide gas by using certain types of catalysts. The district court had ruled that section 271(f) did not apply to process claims. On that basis, it excluded evidence that Shell Oil exported catalysts abroad.

The Federal Circuit held that the district court had erred by excluding the evidence, and it remanded for additional findings on section 271(f) liability. The court analogized the case to *Eolas*, noting that both involved the exportation of a component used in the performance of a patented process. 425 F.3d at 1379. It also noted that the case presented an even stronger basis for applying section 271(f) than *AT&T v. Microsoft* since Shell Oil's foreign affiliates did not copy the catalysts for use abroad but used the catalysts supplied directly by Shell. *Id.* In addition, the court explicitly asked and answered the basic question:

> In other words, does this phrase ["any component of a patented invention"] apply to components used in the performance of patented process/method inventions? *Eolas Techs. v. Microsoft Corp.*, 399 F.3d 1325, 1339 (Fed. Cir. 2005) recently answered this question in the affirmative, holding that *every* component of *every* form of invention deserves the protection of 35 U.S.C. § 271(f); *i.e.*, that "components" and "patented inventions" under § 271(f) are not limited to physical machines.

Id. at 1378-79 (emphases in original). The court distinguished its earlier decision in *NTP, Inc. v. Research in Motion, Ltd.*, where it had held that

section 271(f) did not apply to infringement of a method claim by devices that were domestically manufactured and sold even though their systems operated partially abroad. See 418 F.3d 1282. The *Shell Oil* court reasoned that the infringer in *NTP* had not supplied or combined any components abroad, while Shell Oil had.

St. Jude argues that the *Shell Oil* panel simply erred or, at the very least, that the case is distinguishable on its facts. Several patent law associations and at least three Federal Circuit judges believe that section 271(f) was not intended to apply to method claims. See *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 434 F.3d 1357, 1358-59 (Fed. Cir. 2006) (Lourie, J., Michel, C.J., and Linn, J., dissenting from order denying rehearing *en banc*); Remand Docket No. 138, St. Jude Exs. 36 & 37 (*amicus* briefs in support of petition for rehearing, filed by American Intellectual Property Law Association, Federal Circuit Bar Association, and Federation Internationale des Conseils en Propriete Industrielle). As the court noted in *NTP*, "it is difficult to conceive of how one might supply or cause to be supplied all or a substantial portion of the steps of a patented method in the sense contemplated by the phrase 'components of a patented invention' in section 271(f)." 418 F.3d at 1322. In addition, Shell Oil had combined its exported catalysts with gases in executing the claimed process. St. Jude's ICDs sold abroad are not combined with other physical components to practice the claimed method.

Nevertheless, on the authority of *Eolas*, *AT&T Corp.*, and especially *Shell Oil*, this court cannot

conclude as a matter of law that section 271(f) does not apply to the method claim at issue here. St. Jude's devices are sold directly to foreign customers for (the court must assume) use of the patented method abroad. The court denies St. Jude's motion for summary judgment on the issue, but remains open to considering the issue again if addressed by subsequent case law. Also, if the question remains open at the time of trial, the court will attempt to use procedures that would require the jury to identify specifically any damages attributable to such foreign sales of devices that were capable of infringing use, so that it would be easy to correct any such error.

Conclusion

For the foregoing reasons, the court intends to interpret the disputed elements of Claim 4 of the '288 patent as indicated in this Entry. The court denies CPI's motion for summary judgment on St. Jude's second, fourth, fifth, sixth, and seventh affirmative defenses and its related counterclaims (Remand Docket No. 57). The court denies St. Jude's motion as to CPI's claim for lost profits (Remand Docket No. 77), and grants in part and denies in part its motion to limit CPI's damages to ICDs shown to have used the claimed method in the United States (Remand Docket No. 79).

So ordered.

Date: March 1, 2006

/s/ David F. Hamilton
DAVID F. HAMILTON, JUDGE
United States District Court
Southern District of Indiana